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<p>(21) International Application Number: PCT/US97/13980</p> <p>(22) International Filing Date: 12 August 1997 (12.08.97)</p> <p>(30) Priority Data:</p> <table> <tr> <td>08/689,773</td> <td>13 August 1996 (13.08.96)</td> <td>US</td> </tr> <tr> <td>08/882,397</td> <td>25 June 1997 (25.06.97)</td> <td>US</td> </tr> <tr> <td>08/906,914</td> <td>6 August 1997 (06.08.97)</td> <td>US</td> </tr> </table> <p>(71) Applicant: HEARTSTENT, LLC [US/US]; 651 Campus Drive, St. Paul, MN 55112 (US).</p> <p>(72) Inventors: KNUDSON, Mark, B.; 1309 West Royal Oaks Drive, Shoreview, MN 55126 (US). GIESE, William, L.; Apartment 418, 850 North Randolph Street, Arlington, VA 22203 (US).</p> <p>(74) Agent: BRUESS, Steven, C.; Merchant, Gould, Smith, Edell, Welter & Schmidt, P.A., 3100 Norwest Center, 90 South Seventh Street, Minneapolis, MN 55402-4131 (US).</p>		08/689,773	13 August 1996 (13.08.96)	US	08/882,397	25 June 1997 (25.06.97)	US	08/906,914	6 August 1997 (06.08.97)	US	<p>(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> </p>	
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<p>(54) Title: METHOD AND APPARATUS FOR PERFORMING CORONARY ARTERY BYPASS SURGERY</p>												
<p>(57) Abstract</p> <p>A method and apparatus for performing coronary artery bypass surgery establishes a channel leading directly from a chamber of a heart into a coronary artery with said channel retained open during both diastole and systole. The coronary artery bypass procedure may be performed with or without cardiopulmonary bypass.</p>												

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**METHOD AND APPARATUS FOR PERFORMING
CORONARY ARTERY BYPASS SURGERY**

BACKGROUND OF THE INVENTION

5 1. Field of the Invention.

The present invention relates generally to a method and apparatus for performing a coronary artery bypass procedure. More particularly, the present invention performs a coronary artery bypass by providing a direct flow path from a heart chamber to the coronary artery. The present invention is suitable for a number 10 of approaches including an open-chest approach (with and without cardiopulmonary bypass), a closed-chest approach under direct viewing and/or indirect thoracoscopic viewing (with and without cardiopulmonary bypass), and an internal approach through catheterization of the heart and a coronary arterial vasculature without direct or indirect viewing (with and without cardiopulmonary bypass).

15

2. Description of the Prior Art.

A. Coronary Artery Disease

Coronary artery disease is the leading cause of premature death in industrialized societies. The mortality statistics tell only a portion of the story.

20 Many who survive face prolonged suffering and disability.

Arteriosclerosis is "a group of diseases characterized by thickening and loss of elasticity of arterial walls." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 137 (27th ed. 1988). Arteriosclerosis "comprises three distinct forms: atherosclerosis, Monckeberg's arteriosclerosis, and arteriolosclerosis." *Id.*

25 Coronary artery disease has been treated by a number of means. Early in this century, the treatment for arteriosclerotic heart disease was largely limited to medical measures of symptomatic control. Evolving methods of diagnosis, coupled with improving techniques of post-operative support, now allow the precise localization of the blocked site or sites and either their surgical re-opening or bypass.

30 B. Angioplasty

The re-opening of the stenosed or occluded site can be accomplished by several techniques. Angioplasty, the expansion of areas of narrowing of a blood

vessel, is most often accomplished by the intravascular introduction of a balloon-equipped catheter. Inflation of the balloon causes mechanical compression of the arteriosclerotic plaque against the vessel wall.

Alternative intravascular procedures to relieve vessel occlusion include 5 atherectomy, which results in the physical desolution of plaque by a catheter equipped with a removal tool (e.g., a cutting blade or high-speed rotating tip). Any of these techniques may or may not be followed by the placement of a mechanical support (i.e., a stent) which physically holds open the artery.

Angioplasty, and the other above-described techniques (although less 10 invasive than coronary artery bypass grafting) are fraught with a correspondingly greater failure rate due to intimal proliferation. Contemporary reports suggest re-stenosis is realized in as many as 25 to 55 percent of cases within 6 months of successful angioplasty. See Bojan Cercek et al., 68 AM. J. CARDIOL. 24C-33C (Nov. 4, 1991). It is presently believed stenting can reduce the re-stenosis rate.

15 A variety of approaches to delay or prevent re-blockage have evolved. One is to stent the site at the time of balloon angioplasty. Another is pyroplasty, where the balloon itself is heated during inflation. As these alternative techniques are relatively recent innovations, it is too early to tell just how successful they will be in the long term. However, because re-blockage necessitates the performance of 20 another procedure, there has been renewed interest in the clearly longer-lasting bypass operations.

C. Coronary Artery Bypass Grafting

i. Outline of Procedure

The traditional open-chest procedure for coronary artery bypass grafting 25 requires an incision of the skin anteriorly from nearly the neck to the navel, the sawing of the sternum in half longitudinally, and the spreading of the ribcage with a mechanical device to afford prolonged exposure of the heart cavity. If the heart chamber or a vessel is opened, a heart-lung, or cardiopulmonary bypass, procedure is usually necessary.

30 Depending upon the degree and number of coronary vessel occlusions, a single, double, triple, or even greater number of bypass procedures may be

necessary. Often each bypass is accomplished by the surgical formation of a separate conduit from the aorta to the stenosed or obstructed coronary artery at a location distal to the diseased site.

5

ii. Limited Number of Available Grafts

The major obstacles to coronary artery bypass grafting include both the limited number of vessels that are available to serve as conduits and the skill required to effect complicated multiple vessel repair. Potential conduits include the two saphenous veins of the lower extremities, the two internal thoracic (mammary) 10 arteries under the sternum, and the single gastroepiploic artery in the upper abdomen.

Newer procedures using a single vessel to bypass multiple sites have evolved. This technique has its own inherent hazards. When a single vessel is used to perform multiple bypasses, physical stress(e.g., torsion) on the conduit vessel can 15 result. Such torsion is particularly detrimental when this vessel is an artery. Unfortunately, attempts at using artificial vessels or vessels from other species (xenografts), or other non-related humans (homografts) have been largely unsuccessful. *See LUDWIG K. VON SEGESSER, ARTERIAL GRAFTING FOR MYOCARDIAL REVASCULARIZATION: INDICATIONS, SURGICAL TECHNIQUES AND 20 RESULTS 38-39 (1990).*

While experimental procedures transplanting alternative vessels continue to be performed, in general clinical practice, there are five vessels available to use in this procedure over the life of a particular patient. Once these vessels have been sacrificed or affected by disease, there is little or nothing that modern medicine can 25 offer. It is unquestionable that new methods, not limited by the availability of such conduit vessels, are needed.

iii. Trauma of Open Chest Surgery

In the past, the normal contractions of the heart have usually been stopped during suturing of the bypass vasculature. This can be accomplished by either 30 electrical stimulation which induces ventricular fibrillation, or through the use of

certain solutions, called cardioplegia, which chemically alter the electrolyte milieu surrounding cardiac muscles and arrest heart activity.

Stoppage of the heart enhances visualization of the coronary vessels and eliminates movement of the heart while removing the need for blood flow through 5 the coronary arteries during the procedure. This provides the surgeon with a "dry field" in which to operate and create a functional anastomosis.

After the coronary artery bypass procedure is completed, cardioplegia is reversed, and the heart electrically stimulated if necessary. As the heart resumes the systemic pumping of blood, the cardiopulmonary bypass is gradually withdrawn.

10 The separated sternal sections are then re-joined, and the overlying skin and saphenous donor site or sites (if opened) are sutured closed.

The above-described procedure is highly traumatic. Immediate post-operative complications include infection, bleeding, renal failure, pulmonary edema and cardiac failure. The patient must remain intubated and under intensive post-15 operative care. Narcotic analgesia is necessary to alleviate the pain and discomfort.

iv. Post-Operative Complications

Once the immediate post-surgical period has passed, the most troubling complication is bypass vessel re-occlusion. This has been a particular problem with bypass grafting of the left anterior descending coronary artery when the saphenous 20 vein is employed.

Grafting with the internal thoracic (internal mammary) artery results in a long-term patency rate superior to saphenous vein grafts. This is particularly the case when the left anterior descending coronary artery is bypassed. Despite this finding, some cardiothoracic surgeons continue to utilize the saphenous vein because 25 the internal thoracic artery is smaller in diameter and more fragile to manipulation. This makes the bypass more complex, time-consuming, and technically difficult. Additionally, there are physiological characteristics of an artery (such as a tendency to constrict) which increase the risk of irreversible damage to the heart during the immediate period of post-surgical recovery.

30 Once the patient leaves the hospital, it may take an additional five to ten weeks to recover completely. There is a prolonged period during which trauma to

the sternum (such as that caused by an automobile accident) can be especially dangerous. The risk becomes even greater when the internal thoracic artery or arteries, which are principle suppliers of blood to the sternum, have been ligated and employed as bypass vessels.

5

v. Less Invasive Procedures

Due to the invasive nature of the above technique, methods have been devised which employ contemporary thoracoscopic devices and specially-designed surgical tools to allow coronary artery bypass grafting by closed-chest techniques.

While less invasive, all but the most recent closed-chest techniques still require

10 cardiopulmonary bypass, and rely on direct viewing by the surgeon during vascular anastomoses.

These methods require a very high level of surgical skill together with extensive training. In such situations, the suturing of the bypassing vessel to the coronary artery is performed through a space created in the low anterior chest wall 15 by excising the cartilaginous portion of the left fourth rib. Also, as they continue to rely on the use of the patient's vessels as bypass conduits, the procedures remain limited as to the number of bypasses which can be performed. Because of these issues, these methods are not yet widely available.

vi. Objectives for Improved Bypass Procedures

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In view of the above, it is desirable to provide other methods by which adequate blood flow to the heart can be re-established and which do not rely on the transposition of a patient's own arteries or veins. Preferably, such methods will result in minimal tissue injury.

25

While the attainment of the foregoing objectives through an open chest procedure would, by themselves, be a significant advance, it is also desirable if such methods would also be susceptible to surgical procedures which do not require opening of the chest by surgical incision of the overlying skin and the division of the sternum. Such methods would not require surgical removal of cartilage associated with the left fourth rib, would not require the surgical transection of one or both 30 internal thoracic arteries, would not require the surgical incision of the skin overlying one or both lower extremities, and would not require the surgical

transection and removal of one or both saphenous veins. In both an open and closed chest approach, it is also be desirable if such methods could be performed without stoppage of the heart and without cardiopulmonary bypass. However, attainment of the foregoing objectives in a procedure requiring cardiopulmonary bypass would 5 still be a significant advance in the art.

vii. References for Prior Art Techniques

The conventional surgical procedures (such as those described above) for coronary artery bypass grafting using saphenous vein or internal thoracic artery via an open-chest approach have been described and illustrated in detail. *See generally* 10 10 Stuart W. Jamieson, *Aortocoronary Saphenous Vein Bypass Grafting*, in ROB & SMITH'S OPERATIVE SURGERY: CARDIAC SURGERY, 454-470 (Stuart W. Jamieson & Norman E. Shumway eds., 4th ed. 1986); LUDWIG K. VON SEGESSER, ARTERIAL GRAFTING FOR MYOCARDIAL REVASCULARIZATION: INDICATIONS, SURGICAL 15 TECHNIQUES AND RESULTS 48-80 (1990). Conventional cardiopulmonary bypass techniques are outlined in Mark W. Connolly & Robert A. Guyton, *Cardiopulmonary Bypass Techniques*, in HURST'S THE HEART 2443-450 (Robert C. Schlant & R. Wayne Alexander eds., 8th ed. 1994). Coronary artery bypass grafting utilizing open-chest techniques but without cardiopulmonary bypass is described in Enio Buffolo et al., *Coronary Artery Bypass Grafting Without Cardiopulmonary 20 Bypass*, 61 ANN. THORAC. SURG. 63-66 (1996).

Some less conventional techniques (such as those described above) are performed by only a limited number of appropriately skilled practitioners. Recently developed techniques by which to perform a coronary artery bypass graft utilizing thoracoscopy and minimally-invasive surgery, but with cardiopulmonary bypass, are 25 described and illustrated in Sterman et al., U.S. Patent No. 5,452,733 (1995). An even more recent coronary artery bypass procedure employing thoracoscopy and minimally-invasive surgery, but without cardiopulmonary bypass, is described and illustrated by Tea E. Acuff et al., *Minimally Invasive Coronary Artery Bypass Grafting*, 61 ANN. THORAC. SURG. 135-37 (1996).

D. Bypass With Direct Flow From Left Ventricle

1. Summary of Procedures

Certain methods have been proposed to provide a direct blood flow path from the left ventricle directly through the heart wall to the coronary artery. These 5 are described in U.S. Patent Nos. 5,429,144 dated July 4, 1995; 5,287,861 dated February 22, 1994; and 5,409,019 dated April 25, 1995 (all to Wilk). All of these techniques include providing a stent in the heart wall to define a direct flow path from the left ventricle of the heart to the coronary artery.

As taught in each of the above-referenced patents, the stent is closed during 10 either systole or diastole to block return flow of blood from the coronary artery during the heart's cycle. For example, the '861 patent teaches a stent which collapses to a closed state in response to heart muscle contraction during systole. The '019 patent (particularly Figs. 7A and 7B) teaches a rigid stent (i.e., open during systole) with a one-way valve which closes during diastole to block return flow of blood 15 from the coronary artery.

ii. Problems

The interruption of blood flow during either diastole or systole is undesirable since such interruption can result in areas of stagnant or turbulent blood flow. Such 20 areas of stagnation can result in clot formation which can result in occlusion or thrombi breaking lose. Such thrombi can be carried to the coronary arteries causing one or more areas of cardiac muscle ischemia (myocardial infarction) which can be fatal. Further, the teachings of the aforementioned patents direct blood flow with a substantial velocity vector orthogonal to the axis of the coronary artery. Such flow can damage the wall of the coronary artery.

25 Providing direct blood flow from the left ventricle of the coronary artery has been criticized. For example, Munro et al., *The Possibility of Myocardial Revascularization By Creation of a Left Ventriculocoronary Artery Fistula*, 58 Jour. Thoracic and Cardiovascular Surgery, 25-32 (1969) shows such a flow path in Fig. 1. Noting a fall in coronary artery flow and other adverse consequences, the authors 30 concluded "that operations designed to revascularize the myocardium direct from the

cavity of the left ventricle make the myocardium ischemic and are unlikely to succeed." *Id* at 31.

Notwithstanding the foregoing problems and scholarly criticism, and as will be more fully described, the present invention is directed to an apparatus and method

5 for providing a direct blood flow path from a heart chamber to a coronary artery downstream of an obstruction. Counter to the teachings of the prior art, the present invention provides substantial net blood flow to the coronary artery.

E. Additional Techniques

Methods of catheterization of the coronary vasculature, techniques utilized in 10 the performance of angioplasty and atherectomy, and the variety of stents in current clinical use have been summarized. *See generally* Bruce F. Waller & Cass A. Pinkerton, *The Pathology of Interventional Coronary Artery Techniques and Devices*, in 1 TOPOL'S TEXTBOOK OF INTERVENTIONAL CARDIOLOGY 449-476 (Eric J. Topol ed., 2nd ed. 1994); *see also* David W. M. Muller & Eric J. Topol, *Overview 15 of Coronary Atherectomy*, in 1 TOPOL'S TEXTBOOK OF INTERVENTIONAL CARDIOLOGY at 678-684; *see also* Ulrich Sigwart, *An Overview of Intravascular Stents: Old & New*, in 2 TOPOL'S TEXTBOOK OF INTERVENTIONAL CARDIOLOGY at 803-815.

Direct laser canalization of cardiac musculature (as opposed to canalization 20 of coronary artery feeding the cardiac musculature) is described in Peter Whittaker et al., *Transmural Channels Can Protect Ischemic Tissue: Assessment of Long-term Myocardial Response to Laser- and Needle-Made Channels*, 94(1) CIRCULATION 143-152 (Jan. 1, 1996). Massimo et al., *Myocardial Revascularization By a New Method of Carrying Blood Directly From The Left Ventricular Cavity Into The 25 Coronary Circulation*, 34 Jour. Thoracic Surgery 257-264 (1957) describes a T-shaped tube placed within the ventricular wall and protruding into the cavity of the left ventricle. Also, Vineberg et al., *Treatment of Acute Myocardial Infarction By Endocardial Resection*, 57 Surgery 832-835 (1965) teaches forming a large opening 30 between the left ventricular lumen and the sponge-like network of vessels lying within the myocardium.

SUMMARY OF THE INVENTION

According to the present invention, a method and apparatus for surgically bypassing an obstructed coronary artery establishes a channel leading directly from a chamber of the heart into the obstructed coronary artery at a site distal to the 5 obstruction and holding the channel open during both systole and diastole. Additionally, the apparatus of the invention avoids impingement of high velocity blood flow directly against the coronary artery wall.

The present invention is particularly useful for coronary artery bypass procedures in a patient suffering from obstructive coronary artery disease. The 10 present invention permits an array of procedures of varying invasiveness.

The present invention avoids the previous limitations on the number of performable bypass procedures. Due to the limited number of arteries and/or veins available, standard procedures become increasingly risky to repeat. Rather than relying on harvested veins and arteries as bypass conduits, the present invention 15 forms a channel (or conduit) which leads directly from a chamber of a patient's heart into a coronary artery at a site distal to the obstruction or narrowing.

In the most preferred embodiment, the left ventricle is the chamber of the heart utilized. There are two reasons for this selection. First, the left ventricle normally provides blood to the coronary arteries, because it pumps blood into the 20 aorta from which the coronary arteries branch. Therefore, the magnitude of the blood pressure peak generated by the left ventricle is most similar to the blood pressure peak the proximal coronary artery would normally experience. Second, the blood which flows into the left ventricle is returning from the lungs. In the lungs, the blood acquires oxygen and loses carbon dioxide. Thus, the blood available by 25 shunting from the chambers of the left side of the heart will have a higher oxygen and lower carbon dioxide content than blood within the right-side heart chambers.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a right, front and top perspective view of an L-shaped conduit for 30 use in the present invention;

FIG. 1B is a side elevation view of the apparatus of **FIG. 1A** shown partially in section to reveal an optional bi-directional flow regulator located in a lumen of an anchor arm of the conduit;

FIG. 1C is a side elevation view of a conduit similar to that of **FIG. 1A** 5 showing the addition of a capacitance pressure reservoir as an alternative embodiment;

FIG. 2A is a right, front and top perspective view of a T-shaped conduit according to the present invention;

FIG. 2B is a side elevation view of the conduit of **FIG. 2A** shown partially 10 in section to reveal an optional bi-directional flow regulator located in a lumen of an anchor arm of the conduit;

FIG. 2C is a side elevation view of the conduit of **FIG. 2A** shown partially in section to reveal one optional bi-directional flow regulator located in the lumen of the anchor arm of the conduit, and another optional bi-directional flow regulator 15 located in an intracoronary arm of the conduit;

FIG. 2D is a side elevation view of a conduit similar to that of **FIG. 2A** showing the addition of a capacitance pressure reservoir as an alternative embodiment;

FIG. 3A is a partial side elevation view of a conduit similar to that of **FIGS. 20 1A and 2A** shown partially in section to reveal a flexible anchor arm with rigid rings ensheathed in a flexible covering as an alternative embodiment;

FIG. 3B is a partial side elevation view of a conduit similar to that of **FIG. 3A** shown in section in an extended form;

FIG. 3C is a partial side elevation view of a conduit similar to that of **FIG. 25 3A** shown in section in a compressed form;

FIG. 4 is an anterior view of a human chest which is incised longitudinally to reveal a dissected pericardium and mediastinal contents;

FIG. 5 is a magnified view of an area circled 200 in **FIG. 4** illustrating a longitudinally incised coronary artery;

FIG. 6 is a partial external perspective view of a transversely sectioned 30 coronary artery and heart wall illustrating a channel leading from a lumen of a

coronary artery and into a chamber of the heart according to the method of the present invention;

5 **FIG. 7** is a partial external perspective view of a transversely sectioned coronary artery and heart wall illustrating the partial placement of one embodiment of the conduit of the present invention into the incised coronary artery and formed channel illustrated in **FIG. 6**;

10 **FIG. 8** is a partial external perspective view of a transversely sectioned coronary artery and heart wall illustrating the completed placement of one embodiment of the conduit of the present invention into the incised coronary artery and formed channel illustrated in **FIG. 6**;

FIG. 9 is a partial external perspective view of a sutured coronary artery and phantom view of the conduit of the present invention;

15 **FIG. 10** is a schematic illustration of the use of an endovascular catheter to catheterize the patient's coronary artery;

20 **FIG. 11A** is a cutaway side elevation view of the coronary artery of the bypass procedure illustrating an intravascular catheter with distally-located stent prior to inflation of a catheter balloon underlying the stent;

FIG. 11B is a cutaway side elevation view of the coronary artery of the bypass procedure illustrating the intravascular catheter with distally-located stent following inflation of the catheter balloon underlying the stent;

FIG. 11C is a cutaway side elevation view of a coronary artery illustrating the stent seated to the walls of the coronary artery and the catheter partially withdrawn following deflation of the catheter balloon;

25 **FIG. 12** is a schematic illustration with the heart in partial cutaway of the use of an endovascular catheter to catheterize the patient's left ventricle.

FIG. 13A is a cutaway view of the left ventricle and a partial cutaway view of the coronary artery with seated stent illustrating the formation of a channel into the wall of the left ventricle;

30 **FIG. 13B** is a cutaway view of the left ventricle and a partial cutaway view of the coronary artery with seated stent illustrating a completed channel through the

wall of the left ventricle and deep wall of the coronary artery at the chosen bypass site;

5 **FIG. 14A** is a cross-sectioned view of the left ventricle and a partial cutaway view of the coronary artery with seated stent illustrating the placement of the second intraventricular catheter within the formed channel;

FIG. 14B is a cross-sectioned view of the left ventricle and a partial cutaway view of the coronary artery with seated stent illustrating a blockage of the formed channel by the re-inflated balloon of the intracoronary catheter;

10 **FIG. 14C** is a cross-sectioned view of the left ventricle and a partial cutaway view of the coronary artery with seated stent illustrating an inflation of the balloon located on the distal end of the intraventricular catheter and the seating of an overlying spiral-shaped device against the walls of the formed channel;

15 **FIG. 14D** is a cross-sectioned view of the left ventricle and a partial cutaway view of the coronary artery with seated stent illustrating the device in its locked cylindrical shape seated against the channel walls and the partially withdrawn second intraventricular catheter;

FIG. 15A is a right anterior superior perspective view of the device placed within the formed channel in its spiral shape;

20 **FIG. 15B** is a right anterior superior perspective view of the device placed within the formed channel in its cylindrical form;

FIG. 16 is a cross-sectional view of an interlocking mechanism of the device of **FIGS. 15A** and **15B** in its locked position;

25 **FIG. 17A** is a cross-sectioned view of the left ventricle and a partial cutaway view of the coronary artery, with the device shown in **FIGS. 15A** and **15B** seated within the formed channel, illustrating the introduction of a third intraventricular catheter into the formed channel;

30 **FIG. 17B** is a cross-sectioned view of the left ventricle and a partial cutaway view of the coronary artery, with the device shown in **FIGS. 15A** and **15B** seated within the formed channel, illustrating a tongue and groove interlocking of the bi-directional flow regulator equipped device to the device seated within the formed channel;

FIG. 18A is a schematic longitudinal cross-sectional view of a bi-directional flow regulator shown in a full flow position.

FIG. 18B is the view of **FIG. 18A** with the bi-directional flow regulator shown in a reduced flow position;

5 **FIG. 18C** is a transverse cross-sectional view of the bi-directional flow regulator of **FIG. 18B**;

FIG. 19A is a schematic cross-section longitudinal view of an alternative embodiment of a bi-directional flow regulator shown in a full flow position;

10 **FIG. 19B** is the view of **FIG. 19A** showing the bi-directional flow regulator in a reduced flow position;

FIG. 19C is a transverse cross-sectional view of the bi-directional flow regulator of **FIG. 19B**;

FIG. 20 is a schematic longitudinal cross-sectional view of a channel defining conduit with an alternative embodiment tapered anchor arm;

15 **FIG. 21** is a schematic longitudinal cross-sectional view of the conduit of **FIG. 1A** in place in a coronary artery;

FIG. 22 is a schematic longitudinal cross-sectional view of a test conduit for animal testing of the invention; and

20 **Fig. 23** is a schematic longitudinal cross-sectional view of a conduit in place in a coronary artery illustrating a deflecting shield to protect the coronary artery.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference now to the various drawing figures in which identical elements are numbered identically throughout, a description of the preferred embodiment of the present invention and various alternative embodiments will now be provided.

A. Detailed Summary of the Preferred Embodiment

The invention departs from the traditional bypass approach. Rather than 30 providing an alternative pathway for blood to flow from an aorta to a coronary artery, the invention provides a blood flow path leading directly from a chamber of a

heart to a coronary artery at a site downstream from the stenosis or occlusion. Unlike U.S. Patent Nos. 5,429,144; 5,287,861 and 5,409,019 and contrary to the teachings of these patents, the ventricular-to-coronary artery blood flow path remains open during both diastole and systole. The surgical placement of the 5 apparatus of the present invention establishes this alternative pathway. Also, and as will be more fully described, the invention includes means for protecting the coronary artery from direct impingement of high velocity blood flow.

While the invention will be described in multiple embodiments and with the 10 description of various surgical procedures for practicing the invention, it will be appreciated that the recitation of such multiple embodiments is done for the purpose of illustrating non-limiting examples of multiple forms which the present invention 15 may take.

The presently preferred embodiment is illustrated in FIG. 1A as an L-shaped conduit 10' with an intracoronary arm 14' to reside in the coronary artery (and 20 opening downstream of an occlusion). The conduit 10' has an anchor arm 12' extending through the heart wall with an opening 12a' in communication with the 25 interior of the left ventricle.

While various minimally invasive surgical procedures are described with 30 respect to alternative embodiments, the presently preferred embodiment places the conduit 10' into a coronary artery through an open-chest approach to be described in greater detail with reference to FIGS. 4 - 9. While minimally invasive procedures are desirable, an open chest procedure is presently preferred due to the already large number of physicians trained and skilled in such procedures thus making the benefits of the present invention more rapidly available to patients who currently lack 35 effective treatment.

While the various embodiments (including the presently preferred embodiment of FIG. 1A) will be described in greater detail, a preliminary description of the invention and its method of use will now be given with reference to FIG. 21 to facilitate an understanding of a detailed description of the invention 40 and the alternate embodiments.

FIG. 21 is a schematic cross-sectional view of a conduit 10' of **FIG. 1A** placed within a coronary artery 30. Coronary artery 30 has a lower surface 40 residing against an external surface of a heart wall 42 surrounding the left ventricle 44.

5 The wall 36 of the artery 30 defines an artery lumen 48 through which blood flows in the direction of arrow A. In the view of **FIG. 21**, an obstruction 34 is shown within the lumen 48. The obstruction 34 acts to reduce the volume of blood flow along the direction of arrow A.

10 The conduit 10' is a rigid, L-shaped tube having an anchor arm 12' with a longitudinal axis X-X and an opening 12a' at an axial end. The conduit 10' may be any suitable device (e.g., rigid tube, lattice stent, etc.) for defining and maintaining a fluid pathway during contraction of the heart.

15 The conduit 10' has an intracoronary arm 14' with a longitudinal axis Y-Y and an opening 14a' at an axial end. Both of arms 12', 14' are cylindrical in shape and define a continuous blood flow pathway 11' from opening 12a' to opening 14a'.

The axes X-X and Y-Y are perpendicular in a preferred embodiment. Alternatively, the axes X-X, Y-Y could define an angle greater than 90° to provide a less turbulent blood flow from arm 12' to arm 14'.

20 The conduit 10' is positioned for the anchor arm 12' to pass through a preformed opening 50 in the heart wall 42 and extending from the lower surface 40 of the coronary artery 30 into the left ventricle 44. The opening 12a' is in blood flow communication with the interior of the left ventricle 44 so that blood may flow from the left ventricle 44 directly into path 11'. The arm 14' is coaxially aligned with the coronary artery 30 and with the opening 14a' facing downstream (i.e., in a 25 direction facing away from obstruction 34).

Blood flow from opening 12a' passes through the pathway 11' and is discharged through opening 14a' into the lumen 48 of the coronary artery 30 downstream of the obstruction 34. The outer diameter of arm 14a' is approximate to or slightly less than the diameter of the lumen 48.

30 The axial length of the anchor arm 12' is preferably greater than the thickness of the heart wall 42 such that a length L protrudes beyond the interior

surface of the heart wall 42 into the left ventricle 44. Preferably, the length L of penetration into the left ventricle 44 is about 1-3 millimeters in order to prevent tissue growth and occlusions over the opening 12a'.

In addition to directing blood flow downstream in the direction of arrow A, 5 the arm 14' holds the conduit 10' within the coronary artery 30 to prevent the conduit 10' from otherwise migrating through the preformed opening 50 and into the left ventricle 44. Additionally, an upper wall 14b' of arm 14' defines a region 15' against which blood flow may impinge. Stated differently, in the absence of an arm 14' or region 15', blood flow would pass through the anchor arm 12' and impinge 10 directly against the upper wall 36 of the coronary artery 30. High velocity blood flow could damage the wall 36, as will be more fully described, resulting in risk to the patient.

The region 15' acts as a shield to protect the coronary artery 30 from such blood flow and to redirect the blood flow axially out of opening 14a' into the 15 coronary artery 30. This is schematically illustrated in Fig. 23. For ease of illustration, the axis X-X of the anchor arm 12' is shown at a non-orthogonal angle with respect to the direction A of blood flow in the coronary artery 30 (axis X-X may be either orthogonal or non-orthogonal to direction A). The vector B of blood flow from the anchor arm 12' has a vector component B' parallel to blood flow A 20 and a vector component B'' perpendicular to direction A. The region 15' is positioned between the wall 36 and anchor arm 12' to prevent the blood flow B with high vector component B'' from impinging upon wall 36. The blood flow deflected off region 15' has a reduced vector component perpendicular to flow direction A and reduced likelihood of damage to the coronary artery 30. The region 15' may be a 25 portion of an intracoronary arm 14' or the arm 14' may be eliminated with the region 15' being an axially spaced extension from arm 12' or a separate shield surgically positioned within the coronary artery.

A portion 17' of the anchor arm 12' extends from the lower surface 40 of the coronary artery 30 and through the lumen 48 to the upper surface 36 to block the 30 cross-section of the coronary artery upstream from opening 14a'. The region 17' acts as a barrier to impede or prevent any dislodged portions of the obstruction 34

from passing the conduit 10' and flowing downstream through the coronary artery 30.

The present invention maintains blood flow through the conduit 10' during both diastole and systole. Therefore, while the net blood flow is in the direction of arrow A, during diastole, blood will flow in a direction opposite of that of arrow A.

The constantly open pathway 11' results in a net flow in the direction of arrow A which is extraordinarily high and sufficient to reduce or avoid patient symptoms otherwise associated with an obstruction 34. Specifically, certain aspects of the apparatus and method of the present invention have been preliminary tested in animal studies. FIG. 22 schematically illustrates the tests as the placement of a test conduit 10* in the coronary artery 30' of a pig. For purposes of the tests, a stainless steel T-shaped conduit 10* is used having aligned openings 14a*, 16a* positioned within the coronary artery 30' and with a third opening 12a* protruding 90° out of the coronary artery 30'. The conduit 10* has a uniform interior diameter of 3 millimeters to correspond in sizing with a 3 millimeter lumen of coronary artery 30'. The third opening 12a* is connected by a 3 millimeter conduit 13 to a 3 millimeter rigid Teflon (PTFE) sleeve 13a which was passed through the heart wall 42' into the left ventricle 44'. The conduit 13 and sleeve 13a do not pass through the coronary artery 30'.

In the view of FIG. 22, the direction of net blood flow is shown by arrow A. A first closure device in the form of a suture loop 300 surrounds the artery 30' adjacent the upstream opening 14a* of the conduit 10*. The loop 300 provides a means for closing the upstream opening 14a* by selectively constricting or opening the loop 300 to selectively open or block blood flow through the coronary artery 30'. The first loop 300 permits the test to simulate blockage of the coronary artery 30' upstream of the conduit 10*.

A flow meter 304 to measure volumetric flow of blood downstream of the conduit 10* is placed adjacent downstream opening 16a*. A second closure device 302 functioning the same as loop 300 is placed on conduit 13 to selectively open or close blood flow through conduit 13.

When the second device 302 is closed and the first device 300 is open, the conduit 10* simulates normal blood flow through a healthy coronary artery 30' and the normal blood flow can be measured by the flow measuring device 304. By opening second device 302 and closing the first device 300, the test conduit 10* can 5 simulate the placement of a conduit such as that in FIG. 21 with an obstruction located on the upstream side of the conduit. The flow meter 304 can then measure flow of blood through the conduit 10* during both diastole and systole.

The results of the tests indicate there is a substantial net forward blood flow (i.e., volumetric forward flow less volumetric retro-flow) with the second device 302 10 remaining open during both diastole and systole and with the first device 300 closed to simulate an obstruction. Specifically, in the tests, net blood flows in excess of 80 percent of normal net forward blood flow were measured. It was also noted that with the second device 302 closed and first device 300 open to simulate normal blood flow, the peak blood flow through the coronary artery 30' occurred during 15 systole. With the first device 300 closed to simulate an obstruction and with the second device 302 open, the peak blood flow occurred at diastole.

The amount of back flow through a conduit can be controlled without the need for providing a valve within the conduit. Conveniently referred to as flow "bias", a volumetric forward flow greater than a volumetric rearward flow can be 20 manipulated through a variety of means including sizing of the interior diameter of the conduit, geometry of the conduit (e.g., taper, cross-sectional geometry and angle) and, as will be more fully discussed, structure to restrict rear flow relevant to forward flow.

The sizing of the interior diameter of the flow pathway 11' can be selected to 25 minimize back flow. As will be more further discussed, the net flow increases with a reduction in the diameter as suggested by simulation modeling of flow through a conduit. One method in which shear rate and flow bias can be controlled is by providing a tapered diameter for a narrower diameter at opening 14a' than at opening 12a'. The selection of the conduit geometry (e.g., an angled anchor arm as 30 shown in Fig. 23 or a tapered geometry as will be discussed with reference to Fig. 20) can be selected to modify the degree to which the conduit is biased to net

forward flow (i.e., the conduit offers less resistance to forward flow than to retro-flow) without stopping or blocking retro-flow.

The substantial net blood flow measured in animal testing through the invention is extraordinarily high when compared to minimum acceptable levels of net blood flow following traditional bypass techniques (i.e., about 25 percent of normal net blood flow). Further, the results are counter-intuitive and contradictory to the prior teachings of the art of U.S. Patent Nos. 5,429,144; 5,287,861 and 5,409,919 and the afore-mentioned Munro et al. article. In addition, the present invention provides a conduit with a shielding area to prevent damaging impingement of blood flow directly onto the coronary artery wall as well as providing a blocking area to prevent the migration of debris from an obstruction to a location downstream of the conduit.

Having provided a summarized version of the present invention with reference to the schematic drawings of FIGS. 21 and 22, a more detailed description of the present invention as well as a detailed description of alternative embodiments and alternative surgical procedures will now be provided.

B. Embodiments with an Open Chest Approach

1. The Apparatus of the Present Invention for Use in the Open Chest Approach

As will be more fully described, the present invention places an apparatus for defining a blood flow conduit directly from a chamber of a heart to a coronary artery downstream of an occluded site. Before describing the surgical methods for placing such an apparatus, an apparatus of the present invention will be described. The apparatus of the present invention can be a variety of shapes or sizes, and is not meant to be limited as to size, shape, construction, material, or in any other way by the following examples in which a preferred embodiment is illustrated.

a. T-Shaped Device

With initial reference to FIGS. 2A, 2B, 2C, 2D and 2E, related embodiments of an apparatus according to the present invention are shown as a rigid T-shaped conduit 10 (a preferred L-shaped conduit 10' having already been summarized and

to be later described in detail). The conduit 10 is hollow and includes two axially-aligned intracoronary arms 14, 16 terminating at open ends 14a, 16a. An anchor arm 12 (having an open end 12a) extends perpendicularly to arms 14, 16. The entire conduit 10 is hollow to define a blood flow conduit 11 providing blood flow 5 communication between open ends 12a, 14a and 16a.

As will be more fully discussed, arms 14 and 16 are adapted to be placed and retained within a lumen of a coronary artery on a downstream side of an occlusion with open ends 14a, 16a in blood flow communication with the lumen. The anchor arm 12 is adapted to extend through and be retained in a heart wall (e.g., a wall of 10 the left ventricle) with the open end 12a in blood flow communication with blood within the chamber. When so placed, the conduit 10 defines a surgically-placed conduit establishing direct blood flow from the heart chamber to the artery. By 15 "direct" it is meant that the blood flow does not pass through the aorta as occurs in traditional bypass procedures. The conduit 10 is sufficiently rigid such that it defines an open blood flow path during both diastole and systole.

b. Optional Forward Flow Bias

While unobstructed back flow is preferred, partially restricted back flow can be provided. As will be more fully described, back flow can be controlled by the geometry of the conduit. The following describes a presently less preferred 20 alternative embodiment for controlling back flow.

FIG. 2B illustrates use of an optional bi-directional flow regulator 22 within the conduit 10 and positioned in anchor arm 12. The bi-directional flow regulator 22 permits unimpeded flow in the direction of arrow A (i.e., from open end 12a to open ends 14a, 16a) while permitting a reduced (but not blocked) reverse flow.

FIG. 2C illustrates the use of a first bi-directional flow regulator 22 as well as a second bi-directional flow regulator 26 in arm 16 near the open end 16a of the apparatus. The second bi-directional flow regulator 26 permits unimpeded blood flow in the direction of arrow B. The second bi-directional flow regulator 26 is used to permit a reduced (but not zero) back flow of blood in an upstream direction within 30 the coronary artery. For example, the coronary artery may not be completely obstructed and may have a reduced flow past an obstruction. The use of the T-

conduit 10 with axially aligned arms 14, 16 takes advantage of such reduced flow and supplements such flow with blood through anchor arm 12. As will be described, the conduit 10 is placed with the arms 14, 16 in the lumen of the artery with opening 16a positioned on the upstream side (i.e., nearest to, but still downstream of, the 5 obstruction).

As indicated above, the flow regulator 22 is a bi-directional flow regulator. By this it is meant that the flow regulator 22 does not block flow of blood in any direction. Instead, the flow regulator 22 permits a first or maximum flow rate in one direction and a second or reduced flow rate in a second direction. The flow regulator 10 is schematically illustrated in FIGS. 18A through 19C. In each of these embodiments, the arrow A indicates the direction of blood flow from the left ventricle to the coronary artery.

FIGS. 18A through 18C illustrate one embodiment of a bi-directional flow regulator 22. FIGS. 19A through 19C illustrate an alternative embodiment of a bi-directional flow regulator 22. The regulator 22 of FIGS. 18A through 18C shows a butterfly valve 222 mounted in the anchor arm 12 of a rigid conduit 10. Valve 222 may be pivoted (in response to blood flow in the direction of arrow A) between a position with the plate 222 generally parallel to the walls 12 of the conduit 10 as illustrated in FIG. 18A. The plate 222 can be rotated (in response to blood flow 20 reverse to arrow A) to a position angled relative to the walls 12 of the conduit 10 as illustrated in FIG. 18B. FIG. 18A may be conveniently referred to as a full flow position. FIG. 18B may be conveniently referred to as a reduced flow position. FIG. 18C is a cross-section of the conduit 10 when the plate 222 is in the reduced flow position.

25 The plate 222 is sized relative to the conduit 10 such that the cross-sectional area of the conduit 10 which remains open is sufficient to permit about 20% of the blood flow (measured volumetrically) to flow back through the conduit 10 in a direction opposite to that of arrow A during diastole. As a result, during systole, blood flow from the heart to the coronary artery urges the plate 222 to the full flow 30 position of FIG. 18A such blood may flow unobstructed through the device to the coronary artery. During systole, the blood (due to pressure differentials between the

coronary artery and the left ventricle) will flow in a direction opposite of that of arrow A causing the plate 222 to rotate to the position of FIG. 18B and 18C. However, even in the reduced flow position, the plate 222 is prevented from moving to a full closed position such that flow through the device is never blocked and 5 instead may proceed with a back flow of about 20% (volumetrically measured) of the normal flow in the direction of A.

FIGS. 19A through 19C show an alternative design of the conduit 10 with the flow regulator 22a in the form of three leafs 222a, 222b, 222c which, in response to blood flow from the left ventricle to the coronary artery, open to a full open 10 position shown in FIG. 19B and move to a restricted flow position in FIGS. 19A and 19C in response to back flow. The leaves 222a, 222b, 222c are provided with openings 223 to permit flow through the leaves 222a, 222b, 222c at all times.

It is believed that providing a back flow of about 20% (20% being a non-limiting example of a presently anticipated desired back flow rate) of the volumetric 15 anterograde flow is necessary. This is essential because it allows the channel of the conduit 10 and the mechanical elements of the flow regulator 22 to be washed by the retrograde flow. This ensures that no areas of stagnant flow occur. Areas of stagnation, if allowed, could result in clot formation which could result in thrombi occluding the conduit or breaking loose. Thrombi could be carried downstream into 20 the coronary arteries to cause one or more areas of cardiac muscle ischemia (i.e., a myocardial infarction) which could be fatal. Back flow necessary to wash the components can be achieved through either a conduit 10 which has a constant opening through both systole and diastole (i.e., conduit 10 of FIG. 2A without the use of a bi-directional flow regulator 22) or with a device coupled with a bi- 25 directional flow regulator 22 (FIGS. 2B-2C) which permits a 20% flow rate back flow during diastole.

c. L-Shaped Device

Preferrably, an L-shaped conduit 10' (FIGS. 1A, 1B, 1C) is used to completely bypass the coronary obstruction. An L-shaped conduit 10' has an anchor 30 arm 12' with an open end 12a'. Unlike conduit 10, conduit 10' has only one intracoronary arm 14' perpendicular to arm 12'. Arm 14' has an open end 14a' and

conduit 10' is hollow to define a continuous fluid pathway 11' from end 12a' to end 14a'. In application, arm 14' is placed within the lumen of an artery. End 14a' faces downstream from an obstruction. Arm 12' is placed through the heart wall with end 12a' in fluid communication with blood within the heart chamber. As 5 illustrated in FIG. 1B, the anchor arm 12' can include a bi-directional flow regulator 22' similar to bi-directional flow regulator 22 of conduit 10.

d. Optional Flexible Anchor Arm

Conduit 10, 10' may be rigid, or have varying flexibilities. Regardless of such flexibility, the conduit 10, 10' should be sufficiently rigid for pathway 11, 11' 10 to remain open during both diastole and systole. FIGS. 3A, 3B and 3C demonstrate one embodiment where the anchor arm (i.e., elements 12, 12' of FIGS. 1A and 2A) is comprised of a number of rings 17 surrounded by a membrane 18. In FIGS. 3A- 3C, only anchor arm 12 is shown. It will be appreciated that anchor arm 12' may be identically constructed.

15 In the embodiment of FIGS. 3A-3C, the rings 17 can be constructed of Teflon, and the surrounding membrane 18 can be constructed of a double-walled Dacron sheath into which the rigid supporting rings 17 are sewn. In this embodiment, the rings 17 provide structural strength. The structural strength maintains an open lumen or conduit 11 leading into the coronary artery by 20 preventing the conduit 11 from collapsing by reason of contraction of the heart muscle surrounding the anchor arm 12. The series of rings 17 provide a degree of flexibility which allows a channel formed through the heart chamber muscular wall (receiving anchor arm 12) to be angled or curved. In addition, the flexibility of the surrounding sheath 18 in concert with the rigid rings 17 will allow the anchor arm 12 25 to expand, FIG. 3B, and contract, FIG. 3C, with the contractions and relaxations of the surrounding cardiac musculature.

It should be noted that, because of the semi-rigid nature of the anchor arm 12 constructed in this manner, a method of attaching that end of the anchor arm in contact with the inner surface of a chamber of a heart can be useful. In the example 30 illustrated, this attaching mechanism 19 is a rigid flange 12a. It will be appreciated

that other mechanisms of attachment, such as suturing, biologically gluing, etc. are alternative options.

e. Optional Blood Reservoir

The apparatus of the present invention (as thus described) provides a path 11 through which blood flows from a chamber of a heart and into a coronary artery. 5 Additionally, such a device can store blood under pressure for a period of time prior to its introduction into a coronary artery. As depicted in the embodiments of FIGS. 1C and 2D, this aspect of the conduit 10, 10' of the present invention is referred to as a capacitance pressure reservoir (CPR) 24, 24'.

10 Blood flow through the normal coronary artery is cyclical. Blood flow is increased during diastole (when the heart muscle is in a relaxing state), and decreases or reverses during systole (when the heart muscle is in a contracting state). See, e.g., F. Kajiyama et al., *Velocity Profiles and Phasic Flow Patterns in the Non-Stenotic Human Left Anterior Descending Coronary Artery during Cardiac Surgery*.

15 27 CARDIOVASCULAR RES. 845-50 (1993).

The pressure gradient across the lumens 12a, 12a', 14a', 16a of the apparatus 10, 10' of the present invention will vary over the cardiac cycle. For example, during systole, the contraction of the heart muscles will generate high relative pressures within the left ventricle.

20 The pressures within the coronary arterioles and capillaries distal to the bypass site can also be high during this time, due to the external compression of the contracting cardiac musculature surrounding these vessels. This is particularly true for the vessels of the microcirculation deep within the heart which serve the endocardium.

25 The optional CPR 24, 24' stores the pressurized blood during systole for delivery to the heart muscles via the coronary circulation during diastole when pressures are reduced. In essence, the CPR 24, 24' serves a function similar to the elastic connective tissue of the thick-walled aorta. The necessary function of the CPR 24, 24' is to store blood under higher pressure, and to later provide that stored 30 blood to the microcirculation when the external pressures on that microcirculation are reduced.

As depicted in FIG. 1C and 2D the bi-directional flow regulators 22, 22' provide full blood flow in the direction of A, which is from a chamber of a heart into the conduit 10, 10' via the lumen 11, 11'. The pressure on the blood within the chamber of a heart will be greatest when the surrounding cardiac musculature is in the contracting phase of the cardiac cycle. Because it is during this phase of the cardiac cycle that the external pressure on the coronary artery microcirculation is also highest, blood flow through the lumen 11, 11' of the conduit 10, 10' could be limited. To counteract this tendency, the conduit 10, 10' is equipped with a reservoir 24, 24' which stores this pressurized blood flowing from a chamber of the heart during the cardiac contraction.

The reservoir, or CPR 24, 24' is schematically illustrated in FIGS 1C, 2D. It can be appreciated that the conduit 10, 10' is provided with a fluid passage 28, 28' in communication with pathway 11, 11'. The passage 28, 28' communicates with an expandable volume (or storage chamber) 27, 27' defined by a movable wall 31, 31' contained within a fixed housing 33, 33'. Springs 29, 29' between wall 31, 31' and housing 33, 33' urge the wall 31, 31' to move to reduce the size of volume 27, 27'. The springs 29, 29' are pre-loaded to exert a force on wall 31, 31' less than a force exerted by blood within volume 27, 27' during the contraction phase of the cardiac cycle, but greater than the force exerted by blood within volume 27, 27' during the relaxation phase of the cardiac cycle.

The conduit 10, 10' is constructed in a manner which allows blood to flow into the storage chamber 27, 27' of the conduit 10, 10' through the lumen 11, 11' of arm 28, 28' of the conduit when the cardiac musculature is contracting. When blood is flowing into the storage chamber 27, 27', the kinetic energy of the flowing blood is converted to potential energy, and stored in 29, 29'. During the relaxation phase of the cardiac musculature, the potential energy stored in 29, 29' of the CPR 24, 24' is then re-converted to kinetic energy in the form of blood flow out of the storage chamber 27, 27' of the conduit 10, 10' via the lumen 11, 11' of arm 28, 28' of the conduit.

While the CPR 24, 24' is illustrated with a movable wall 31, 31' and springs 29, 29' to define a variable volume, other designs can be used. For example, the

CPR 24, 24' can be a balloon-like structure. As it fills with blood, the pressure on that blood increases through the stretching of an elastic component of a balloon. In another embodiment, the CPR, 24, 24', can be a hollow bag, made of a material which is elastic, but impermeable to liquids, and pliable similar to a plastic bag.

5 When the heart contracts, blood is forced through lumen 11, 11' of arm 28, 28' of the apparatus 10, 10' of the invention into the collection bag.

The incorporation of bi-directional flow regulators 22, 22' within the anchoring arm 12, 12' of the conduit 10, 10' provide most (about 80%) of the flow of blood out of the device during diastole to the coronary artery via the lumen 11'

10 11' of arms 14a, 14a', 16a of the device, of the conduit 10, 10'. Similarly, the incorporation of the bi-directional flow regulator 26 within the intracoronary arm 16 of the T-shaped conduit 10, when employed with the bi-directional flow regulator 22 within the anchor arm 20 of the conduit 10, would provide most of the flow of blood out of the device during diastole to the portion of the coronary artery distal to the

15 bypass site via the downstream lumen 11 of arm 14a.

f. Sizing of the Conduit

The inner and outer cross-sectional diameters of a coronary artery decreases with the distance from the arterial origin. Eventually, the artery branches into a number of arterioles, which feed the capillary bed of the coronary arterial

20 microcirculation.

The typical diameter of a lumen of a coronary artery is, in general, species specific; increasing with heart size. In humans, this lumen diameter is dependent upon which artery is being evaluated, but usually ranges from 1.0 to 4 mm in diameter, and decreases with distance from the aortic origin. In the preferred 25 embodiment, the cross-sectional outer diameter of the intracoronary arms 14, 14', 16 of the device of the present invention should effectively approximate the diameter of the lumen of the coronary artery being bypassed, at the bypass site. This allows the complete re-approximation of the previously opened superficial wall of the coronary artery during surgical closure, without high suture or staple tension resulting. In the 30 most preferred embodiment, the outer diameter of the intracoronary arms 14, 14', 16 of the conduit 10, 10' of the present invention is equal to the diameter of the lumen

of the coronary artery which is being bypassed, at the bypass location. When a CPR is placed, the artery wall may need to be expanded by the addition of a patch, such as Dacron, well known in the art.

Also, due to smooth muscle relaxation and secondary vascular dilation, the 5 cross-sectional diameter of a lumen of a coronary artery will increase with the oxygen demand of cardiac muscle during times of stress. The cross-sectional inner diameter of the intracoronary arms 14, 14', 16 of the conduit 10, 10' of the present invention should effectively approximate that diameter necessary to provide adequate blood flow through the downstream lumen of the conduit to effectively 10 oxygenate the cardiac musculature normally supplied by the microcirculation of the coronary artery. In the preferred embodiment, the cross-sectional inner diameter of the intracoronary arms 14, 14', 16 of the conduit 10, 10' of the present invention should effectively approximate that diameter necessary to provide adequate blood flow through the lumen of the device to effectively oxygenate the cardiac 15 musculature normally supplied by the microcirculation of the coronary artery during both times of cardiovascular resting and stress.

If necessary, an initial approximation of the required cross-sectional outer diameter of the intracoronary arms 14, 14', 16 of the conduit 10, 10' of the present invention can be gained by standard radiographic techniques. Also, in the 20 alternative embodiment apparatus when a bi-directional flow regulator 22, 22' is desired, the operating pressure of the bi-directional flow regulator 22, 22' (i.e., the pressure at which the flow regulator moves from a reduced back-flow to a full forward flow position) can be determined by the dynamic measurements of coronary artery pressure, blood flow, and heart chamber pressures through selective 25 catheterization with standard techniques. See Minoru Hongo et al., 127(3) AM. HEART J. 545-51 (March 1994).

During the coronary artery bypass procedure, the most appropriate sizing of the intracoronary arms 14, 14', 16 of the conduit 10, 10' of the present invention can be re-assessed. This can be accomplished by probing the distal and, if needed, the 30 proximal aspects of the coronary artery at the chosen bypass site with blunt instruments of known outer diameters. Such sizing by probes is well-known in the

literature. To facilitate the effective matching of the external diameter of the intracoronary arms 14, 14', 16 of the conduit 10, 10' of the present invention to the lumen 34 of the coronary artery to be bypassed, an assortment of conduits of the present invention of various diameters can be available for the surgeon to select 5 from.

The anchor arm 12, 12' is sized to maximize net blood flow from the left ventricle to the coronary artery. Through simulation testing, a counter-intuitive indication is that maximizing the diameter of anchor arm 12, 12' is not desirable. For example, such simulation assuming diameters of 3.00 mm, 2.25 mm and 1.50 10 mm for an unrestricted fistula (i.e., without a flow regulator 22) suggests that the smaller diameter of 1.50 mm most closely approximates normal coronary blood flow and minimizes back flow thus maximizing net forward flow.

It is desirable that the anchor arm 12, 12' protrudes into the heart chamber such that end 12a is spaced from the heart wall. This prevents tissue growth over 15 end 12a.

Finally, it will be noted that the anchor arm 12 defines a longitudinal axis (e.g., axis X-X in FIG. 18A). The region 15 of arms 14, 14 intersects axis X-X. The region 15 acts as a deflection surface to prevent high velocity blood flow from 20 arm 12 impinging directly upon the coronary artery wall. Instead, the high velocity blood flow impinges upon region 15 and is directed axially into the coronary artery. As a result, the coronary artery wall covered by region 15 is protected from damage which would otherwise be caused by the high velocity blood flow and the blood components are transitioned to axial flow with a minimum of cell damaging shear.

FIG. 20 shows a still further embodiment 10" where the anchor arm 12" has 25 a longitudinal axis X'-X' at a non-orthogonal angle relative to the axis Y'-Y' of the coronary arms 14", 16". Further, the anchor arm 12" has a taper. In other words, the arm 12" is widest at opening 12a". The taper and angle act to reduce blood flow velocity and to restrict back flow (arrows B) while facilitating forward flow (arrow A'). Also, the blood in the forward flow A' impacts against the deflection region 30 15" at an angle to reduce impact of blood cells.

2. The Method of the Present Invention Using the Open Chest Approach

a. General

The method of the present invention is suitable for performing a variety of surgical cardiac procedures. The procedures may be performed utilizing an open-chest approach, or through minimally invasive approaches by the creation of access means into the chest, or through percutaneous access utilizing intracoronary and intraventricular catheterization. Dependent on the invasiveness of the approach utilized, the heart can be allowed to pulse normally, be slowed by varying amounts, or stopped completely. A significant period of complete heart stoppage can necessitate the use of supportive cardiopulmonary bypass.

The method of the present invention for performing a coronary artery bypass procedure will now be described in detail. The patient who is to undergo the procedure can be prepared in a conventional manner for cardiac bypass surgery. The patient preparation, anesthesia utilized, and access route to the coronary circulation, will vary depending upon the invasiveness of the specific procedure chosen.

b. Preparation for the Procedure

i. General Preparations

Standard techniques of general preparation for open-chest surgery in which cardiopulmonary bypass is utilized have been widely reported. See, e.g. LUDWIG K. VON SEGESSER, ARTERIAL GRAFTING FOR MYOCARDIAL REVASCULARIZATION (1990). In one embodiment of the methods of the invention where an open-chest procedure and cardiopulmonary bypass is utilized, the patient can be prepared for surgery as outlined by Von Segesser.

General preparations for open-chest surgery in which cardiopulmonary bypass is not utilized have been published by Buffalo et al., 61 ANN. THORAC. SURG. 63-66(1996). In one embodiment of the methods of the invention where an open-chest procedure without cardiopulmonary bypass is utilized, the patient can be prepared for surgery as outlined by Buffalo.

General preparations for closed-chest surgery, to be performed using thoracoscopy and where cardiopulmonary bypass is utilized, have been outlined by

Sterman et al., U.S. Pat. No. 5,452,733 (1995). In one embodiment of the methods of the invention where a closed-chest procedure and cardiopulmonary bypass is utilized, the patient can be prepared for surgery as outlined by Sterman.

General preparations for closed-chest surgery to be performed using

5 thoracoscopy, but where cardiopulmonary bypass is not utilized, have been published by Acuff et al., 61 ANN. THORAC. SURG. 135-37 (1996). In one embodiment of the methods of the invention where a closed-chest procedure without cardiopulmonary bypass is utilized, the patient can be prepared for surgery as outlined by Acuff.

10 General preparations for percutaneous coronary artery bypass grafting utilizing intracoronary and intraventricular catheterization and without cardiopulmonary bypass have been described by Wilk in his afore-mentioned U. S. patents. Preparations can include the sterile scrubbing and draping of at least one groin to permit access to a femoral artery for catheterization of the coronary

15 vasculature and the sterile scrubbing and draping of the right superior anterior chest wall to permit access to the innominate artery for catheterization of the left ventricle. Further suggested preparations can include those outlined by Sterman and Acuff for thoracoscopic surgery with and without cardiopulmonary bypass, respectively.

ii. Anesthesia Prior to and During the Procedure

20 Most often, the patient will be placed under general anesthesia prior to the procedure. In one embodiment, standard cardiac operative anesthetic techniques, such as premedication with diazepam, induction with propofol and sufentanil, and maintenance with desflurane can be employed. On occasion, less than general anesthesia can be utilized. Less than general anesthesia is well known in the

25 literature. When the invasiveness of the procedure is minimal, such as when the procedure is to be carried out via intracoronary and intraventricular catheterization, or when the risks of general anesthesia to the individual patient outweighs the risks of less than general anesthesia with regard to the particular procedure planned, less than general anesthesia can be induced. Selective ventilation of the lungs can be

30 achieved through the placement of a double-lumen endobronchial tube which independently provides for the intubation of the left and right main stem bronchi.

An intraesophageal probe can be placed to facilitate cardiac monitoring and the synchronization of power to the laser, when deemed useful.

iii. Access to the Heart and Coronary Vasculature for the Procedure

5 Following preparation, access to the patient's coronary arterial vasculature can be attained through a variety of techniques, dependent upon the route of access chosen.

10 Von Segesser has reported a method of access to the coronary arterial vasculature when utilizing an open-chest approach and cardiopulmonary bypass. In one embodiment, utilizing an open-chest approach with cardiopulmonary bypass, access to the coronary vasculature can be obtained as reported by Von Segesser.

15 Buffalo et al. has reported an open-chest approach to the coronary arterial vasculature when performed without cardiopulmonary bypass. See Buffalo et al., 61 ANN. THORAC. SURG. 63-66 (1996). In one embodiment utilizing an open-chest approach without cardiopulmonary bypass, access to the coronary vasculature can be obtained as reported by Buffalo.

20 Sterman et al. has reported a method of access to the coronary arterial vasculature when a closed-chest approach with cardiopulmonary bypass is utilized. See Sterman et al., U.S. Pat. No. 5,452,733 (1995). Sterman positions a plurality of access trocar sheaths along the patient's left and right anterolateral chest wall. These trocar sheaths provide access to the coronary vasculature, and allow the temporary repositioning of the heart to facilitate the performance of the procedure. The repositioning is accomplished utilizing grasping tools introduced through the appropriate trocar sheaths. Visualization during this procedure can be either 25 indirectly via thoracoscopy, or directly via a 'window' placed in the left middle anterior chest wall by the surgical removal of the fourth rib. Access to the bypass site can therefore be obtained by following the techniques outlined by Sterman. The instruments to be used in the procedure can also be similar to those described by Sterman.

30 Acuff et al. has described a method of access to the coronary arterial vasculature when a closed-chest approach without cardiopulmonary bypass is

utilized. *See* Acuff et al., 61 ANN. THORAC. SURG. 135-37 (1996). Similar to the techniques of Sterman, Acuff positions a plurality of access trocar sheaths along the patient's left and right anterolateral chest wall. Also similar to Sterman, Acuff surgically establishes an access space, or window in the left anterior chest wall 5 through the removal of the left fourth rib cartilage. The trocar sheaths, in concert with this window, allow the temporary repositioning of the heart, and access to the coronary arterial vasculature. Visualization during this procedure can be either indirectly via thoracoscopy, or directly via the window. Access to the bypass site can therefore be obtained by following the techniques outlined by Acuff. The 10 instruments to be used in the procedure can also be similar to those described by Acuff.

Access to a chamber of a heart and a coronary artery when the bypass is performed through the percutaneous approach of intracoronary and intraventricular catheterization can be obtained as follows. Access to a coronary artery can be 15 obtained by the introduction of a catheter into the left or right femoral artery through an arterial cut down procedure. The catheter can then be fed retrograde past the descending aorta, through the ascending aorta, and into the coronary artery by standard catheterization techniques. In a preferred embodiment, access to a chamber of the left side of a heart can be obtained by the introduction of a catheter into the 20 innominate artery, also through an arterial cut down procedure. In the most preferred embodiment, access to the left ventricle is obtained by the introduction of a catheter into the innominate artery and the advancement of this catheter into the left ventricle. In this embodiment, the catheter is advanced through the ascending aorta, past the aortic valve, and into the left ventricle. Techniques by which the left 25 ventricle is catheterized are well known in the literature.

3. Open Chest Approach

In the coronary artery bypass graft procedures of the present invention, a chamber of a heart provides blood to a coronary artery. The method of the present invention can accomplish this by establishing one or more channels through the wall 30 of a chamber of a heart which lead directly from a chamber of a heart into a coronary artery at a site distal to the narrowing or blockage. The methods of the invention in

various embodiments can achieve the establishment of such a channel or channels through a variety of techniques.

Referring now to FIGS. 4, 5, 6, 7, 8, and 9, an exemplary open-chest procedure, which may or may not include cardiopulmonary bypass, by which a 5 coronary artery bypass procedure may be accomplished will be described. The open-chest approach affords maximal access to, and visualization of, the coronary vasculature; although at the expense of injury to normal tissue.

Through the methods of the present invention, the conduit 10, 10' of the present invention, which provides blood from a chamber of a heart 43 directly into a 10 coronary artery 30, is placed. To illustrate the invention, only placement of conduit 10' is discussed. It will be appreciated that conduit 10 can be similarly placed. In addition, examples will be limited to the embodiment of the conduit of the invention as illustrated in FIG. 1A.

Preparation for the procedure, and anesthesia prior to and during the 15 procedure, is outlined above.

First, the chest cavity is entered, and pericardium 52 incised anteriorly, to expose a coronary artery 30 (having an obstruction 34) to be bypassed. This is illustrated in Fig. 4.

Second, cardiopulmonary bypass may be initiated by a variety of standard 20 techniques as outlined by George Silvay et al., *Cardiopulmonary Bypass for Adult patients: A Survey of Equipment and Techniques*, 9(4) J. CARDIOTHORAC. VASC. ANESTH. 420-24 (August 1995).

Third, if bypassed, the heart is slowed and/or stopped by a variety of standard techniques. One standard technique is to electrically induce ventricular 25 fibrillation. Another standard technique is warm or cold blood cardioplegia, delivered antegrade or retrograde, and intermittent or continuous, as outlined by Gerald D. Buckberg, *Update on Current Techniques of Myocardial Protection*, 60 ANN. THORAC. SURG. 805-14 (1995).

Fourth, the heart is inspected and coronary arteries identified. The narrowed 30 or occluded coronary artery 30 can be visually identified, and an appropriate site distal or downstream from the occlusion 34 chosen.

Fifth, blood flow through the target coronary artery 30 is halted by standard techniques. For example, standard techniques include clamping the aorta above the coronary ostia with an arterial clamp. Alternatively, in the beating heart procedure, the flow of blood within the coronary artery 30 can be halted by forming a loop

5 around the artery 30 with suture either proximally, or both proximally and distally, and applying appropriate tension on the suture or sutures, or tying the suture or sutures.

Sixth, depending on the degree of exposure deemed necessary, the epicardium overlying the coronary artery at the selected bypass site is incised. This 10 exposure can facilitate locating the lumen of the coronary artery 30 via palpation.

Seventh, as shown in FIG. 5, the superficial wall 36 of the coronary artery 30 is longitudinally incised by standard techniques, such as incision with a scalpel, electrosurgical cutting device, or similar tool; taking care not to damage the deep wall of the artery. This initial incision can be lengthened, if necessary, to 15 accommodate the intracoronary arms 14' using standard tools such as fine angled scissors.

Eighth, a channel 50 is initiated into the deep coronary arterial wall 40 and through the musculature 42 of a chamber of a heart. In the preferred embodiment, the chamber of a heart is the left ventricular chamber of the heart. The channel 50 20 can be initiated by standard techniques such as awl punching, incising, use of a laser, or the like. The channel 50 is then extended into the chamber of a heart, in this case the left ventricle 44, by standard techniques (such as punching with a trocar 46, incising with a scalpel blade, electrosurgical cutting with an electrosurgical cutting tool, laser or radio frequency ablation, blunt dissection, etc.).

25 Ninth, once a channel extending through the entire thickness of a wall 42 of a chamber of a heart is formed, it can be systematically sized by the passage of standard probes.

Tenth, through palpation, inspection, and probing of the distal and proximal 30 coronary artery lumen 48, a conduit 10' of appropriate dimensions is selected, as outlined above.

Eleventh, as illustrated in FIGS. 7 and 8, the anchor arm 12' is inserted into the formed channel 50. The intracoronary arm 14' is then seated within the lumen 48 of the coronary artery 30.

Twelfth, as shown in FIG. 9, the longitudinal incision 38 previously incised 5 in the anterior wall 36 of the coronary artery 30 is surgically re-approximated. The re-approximation can be performed by a number of conventional techniques, including suturing 52, laser welding, microstapling, and the like.

Thirteenth, the clamps or sutures closing off blood flow to the coronary artery are released.

10 Fourteenth, contractions of the heart, if previously stopped, are reinitiated by standard electrostimulation or the reversal of cardioplegia and the patient is slowly weaned from cardiopulmonary bypass by standard techniques.

Fifteenth, the pericardium, sternum, and overlying skin of the chest is re-approximated and surgically closed by standard, conventional techniques.

15 Sixteenth, anesthesia is reversed and the patient revived by standard techniques.

D. Embodiments for a Closed Chest Approach

1. The Apparatus of the Present Invention for Use in the Closed Chest Approach

20 A closed chest approach according to the method of the present invention may use the conduit 10, 10' as described above. Such a procedure will now be described. Following this description, a closed chest approach using alternative embodiments of the apparatus of the invention will be described.

25 2. The Method of the Present Invention Using the Closed Chest Approach

An exemplary closed-chest procedure, without cardiopulmonary bypass, by which a coronary artery bypass may be accomplished will now be described. The closed-chest approach is less invasive than the open-chest approach, although 30 providing the surgeon with somewhat poorer visualization and limited direct access to both the chambers of the heart and coronary artery bypass site.

Preparation for the procedure, and anesthesia prior to and during the procedure, is outlined above.

First, a plurality of access trocar sheaths is positioned anterior and laterally along the left and right chest walls as outlined by Acuff et al.

5 Second, a space in the left low anterior chest wall may be formed by removal of the fourth rib cartilage, as outlined by Acuff et al. In this embodiment, the heart and coronary artery can be both directly viewed via this space or window, as well as indirectly visualized via a thoracoscope.

10 Third, a standard pericardiotomy is performed using a scalpel or electrosurgical cutting tool introduced through the left lateral chest trocar sheaths while viewing under thoroacoscopy. The pericardium can be excised and either spread open, or removed from the thoracic cavity as outlined by Acuff et al.

15 Fourth, if necessary, the heart can be rotated within the mediastinum. Direct access and visualization through the formed chest wall space can require rotation of the heart. Rotation of the heart can be accomplished by the grasping of the heart by tools inserted through access trocar sheaths located along the left and right chest wall as described by Sterman et al. Alternatively, traction on sutures placed in the pericardium can distract the heart allowing appropriate direct visualization of the area to be bypassed as described by Acuff et al. In another alternative procedure, the 20 heart can be accessed from the patient's back with an endoscope for implantation of the stent in the posterior vascular beds which are not currently accessible by minimally invasive techniques.

25 Fifth, once the coronary artery to be bypassed is identified and well- visualized; snare sutures of 5-0 polypropylene are placed at least proximally to the target area as described by Acuff et al.

Sixth, the heart rate can be pharmacologically slowed to approximately 40 beats/minute to minimize motion within the operative field as described by Acuff et al. Nitroglycerin and heparin can also be administered to reduce cardiac ischemia and prevent clotting respectively as outlined by Acuff et al.

30 Because cardiopulmonary bypass is omitted in this embodiment, intermittent coronary artery occlusion to induce ischemic preconditioning, as well as

transesophageal echocardiography to review cardiac wall motion changes, can be utilized as described by Acuff et al. The epicardium can be incised over the area selected for bypass and the anterior surface of the artery cleared under direct visualization through the space or window, or via remote instruments inserted 5 through the trocar sheaths under thoracoscopic guidance.

Seventh, in situations where the coronary artery can be directly viewed, the lumen 48 of the coronary artery is identified by palpation. Either under direct visualization, or under thoracoscopic guidance and using instruments manipulated through the trocar sheaths, the superficial wall 36 of the coronary artery is then 10 longitudinally opened. As above, care is taken to leave the deep wall 40 of the artery undamaged. The incision 38 can be enlarged, as necessary, to accommodate the intracoronary arms 14, 14', 16 of the conduit 10, 10' using fine angled scissors. This enlargement can be performed with standard surgical scissors under direct 15 viewing through the window, or via other surgical instruments remotely manipulated following their insertion through the trocar sheaths.

Eighth, a channel 50 through the heart wall is initiated by incising or laser ablating into the deep wall 40 of the coronary artery. This also can be performed by standard surgical tools under direct viewing, or by the remote manipulation of specialized instruments introduced through the trocar sheaths and viewed 20 thoroscopically. The channel 50 is then extended through the deep coronary arterial wall 40, through underlying cardiac musculature 42, and into the underlying chamber of the heart 44 by incising with a scalpel or electrosurgical cutting blade, laser ablation, blunt dissection, or the like. In the preferred embodiment, a chamber 25 of a heart 44 is one of the two chambers of the left side of the heart. In the most preferred embodiment, a chamber of a heart 44 is the left ventricle.

Ninth, the channel 50 extending through the entire thickness of a muscular wall 42 can be systematically sized by the passage of standard measuring probes. These standard measuring probes, with fixed and known tip diameters, can be 30 similarly used to size and determine the proximal and distal patency of the coronary artery being bypassed.

Tenth, through direct and/or thoracoscopic inspection of the coronary artery lumen 48, or by probing as outlined above, an appropriately dimensioned conduit 10, 10' of the present invention is selected. As in the case of the open-chest approach (outlined above), an array of conduits 10, 10' of various sizes can be 5 available for the operation.

Eleventh, either under direct control and visualization, or by indirect manipulation and thoracoscopic viewing, the anchoring arm 12, 12' of the conduit 10, 10' of the invention is inserted into the formed channel 50. By similar techniques the remaining intracoronary arm or arms 14, 14', 16 of the conduit 10, 10' are seated within the lumen 48 of the coronary artery 30 being bypassed. In one embodiment where the procedure is performed under thoracoscopic viewing, the conduit 10, 10' can be introduced into the cardiac cavity through the space or window previously formed within the anterior inferior aspect of the left chest wall. In this embodiment, the conduit 10, 10' can be grasped, once introduced into the 15 chest cavity, by surgical instruments inserted through the trocar sheaths and remotely manipulated into position. In this manner the anchor arm 12, 12' of the conduit 10, 10' is then inserted into the channel formed 50 via the remote manipulation of these instruments.

Twelfth, the incision present in the superficial wall 38 of the coronary artery 20 30 is closed by conventional surgical techniques such as suturing, laser welding, microstapling, and the like. When closure is by indirect thoracoscopic versus direct viewing, suturing, laser welding, microstapling and the like can be accomplished by utilizing surgical instruments remotely manipulated following their introduction through the trocar sheaths.

25 Thirteenth, upon completion of placement of the conduit 10, 10' of the present invention, the heart, if rotated, can be returned to its normal orientation.

Fourteenth, all heart manipulating devices are removed from the chest cavity.

Fifteenth, contractions of the heart can be allowed to return to their normal resting rate by the discontinuation of intravenous esmolol and diltiazem, if utilized.

Sixteenth, the pericardium 52 is partially or completely re-approximated. An external drain can be placed inside the pericardium, as needed, as described by Acuff et al.

Seventeenth, the trocar sheaths are removed, and all thoracic punctures 5 surgically repaired in a conventional manner.

Eighteenth, anesthesia is reversed and the patient revived by standard techniques.

E. Embodiments with the Catheter-Controlled Approach

10 Referring now to FIGS. 10, 11, 12, 13, 14, 15, and 16, an exemplary coronary artery bypass procedure performed through catheterization will be described. This approach allows no direct visualization of the coronary vasculature, although the chamber of the heart could be indirectly visualized during the procedure by equipping the intraventricular catheter with a standard fiber-optic 15 device, if desired. Because the procedure is performed through catheters introduced remotely, normal tissue injury is minimized.

Preparation for the procedure, and anesthesia prior to and during the procedure, is outlined above.

In the embodiment to be described, cardiopulmonary bypass is unnecessary. 20 However, the procedure would be in no way limited if cardiopulmonary bypass were performed.

First, an intracoronary catheter 120 (FIG. 10) is inserted via an incision in the 25 groin 126 and advanced within the femoral artery 124. Through continued advancement within the descending aorta 128, and the ascending aorta 122, the coronary artery 30 is entered.

Dependent on the degree of narrowing or occlusion of the coronary artery, standard angioplasty, atherectomy, or some similar procedure can be optionally performed if passage of the catheter tip 136 (FIG. 11A) is hindered. Angioplasty, 30 arthrectomy, and the like could optionally precede the catheter-controlled bypass procedure.

If desired, the heart may be slowed while catheterizing the coronary vasculature, during the construction of a channel or channels 50 leading from a chamber of a heart 44 into a lumen of a coronary artery 30 itself, or both. Such slowing can improve visualization of the catheters as facilitated by fluoroscopy or 5 the alternative radiologic techniques by which the procedure can be performed. Standard pharmacologic methods, as described above, to slow the heart are well known in the literature.

Second, the intracoronary catheter 120 is advanced within the coronary arterial vasculature tree to the target location through standard catheter manipulation 10 techniques. The proper location of the intracoronary catheter tip 136 in relation to the targeted bypass site can be determined through standard radiographic techniques.

Third, as shown in FIGS. 11A-11C, a balloon 130 located on the distal end of the intracoronary catheter 120 is inflated (FIG. 11B). Inflation of the balloon 130 causes a stent 134 located circumferentially surrounding the balloon 130 to be seated 15 against the coronary arterial walls 36, 40. The stent 134 is a hollow expandable stent having a cut-out area 135 along the cylindrical wall of the stent 134, for reasons that will become apparent. The stent 134 is positioned at placement within the coronary artery in a manner that the cut-out 135 is juxtaposed against the deep wall 40 of the coronary artery 30 upon inflation of the intracoronary catheter balloon 20 130.

Fourth, the balloon 130 is deflated (FIG. 11C) and the catheter 120 withdrawn into the ascending aorta 122 leaving the expanded stent 134 in place.

Fifth, an intraventricular catheter 140 is inserted into the innominate artery 144 via an incision in the anterior superior right chest wall 142 as shown in FIG. 12. 25 The intraventricular catheter 140 is advanced in a retrograde fashion through the ascending aorta 22, and into the chambers of the left side of the heart. By continued advancement, the intraventricular catheter 140 is extended past the semilunar valves 148 and into the left ventricle 44. Throughout the procedure, the location of the intraventricular catheter 140 within a chamber of a heart 44 can be ascertained by 30 either indirect visualization employing standard fiber-optic instrumentation inherent to the intraventricular catheter, or and/or by standard radiographic techniques.

Sixth, a channel 50 can be ablated (FIGS. 13A-13B) through both a wall of a chamber of a heart 42 and the deep wall of a coronary artery 40 utilizing an ablating tip 132. Such ablating devices are well known in the literature and can include a laser, a radio frequency device, or the like. Power to the ablating tip 132 can be 5 synchronized via the intraesophageal probe such that ablation occurs at a recurring aspect of the cardiac cycle. Such synchronization of devices to physiological function is well-known in the literature. The ablation can be indirectly observed via fiber optics associated with the intraventricular catheter 140. Alternatively, the 10 location of the ablating tip 132 can be determined by standard radiographic techniques.

Seventh, once a channel 50 through the heart chamber wall 42 is formed, the intracoronary catheter 120 is re-advanced into the coronary artery 30.

Eighth, the balloon 130 on the distal end of the intracoronary catheter 120 is re-inflated upon reaching the target bypass site, as illustrated in FIGS. 14A and 14B. 15 Inflation of the intracoronary catheter balloon 130 seals the formed channel 50 so that blood is prevented from flowing from the coronary artery lumen 48, through the formed channel 50, and into a chamber of the heart 44. Note, though, that the inflation of the intracoronary catheter balloon 130 still allows blood to perfuse the downstream portion of the coronary artery 30. This is because the intracoronary 20 catheter 120 is equipped with channels 138 which allow blood to pass internally within the intracoronary catheter 120 from the upstream portion of the coronary artery 30, and to exit the catheter into the downstream portion of the coronary artery 30.

Ninth, the ablating catheter 140 is removed from the body completely.

25 Tenth, a second intraventricular catheter 160 is inserted into the innominate artery 144 at the arterial cut-down site 142, as shown in FIG. 12. The intraventricular catheter 160 is next advanced in a retrograde fashion into the ascending aorta 22. By continued advancement, the intraventricular catheter 160 is finally extended past the semilunar valves 148 and into the left ventricle 44.

This intraventricular catheter is equipped with a inflatable balloon 60 on the catheter's distal end, and a stent-forming device 61 circumferentially surrounding the balloon 60 on the catheter's distal end (FIGS. 14A-14D).

The stent forming device 61 is a spiral sheet shown separately in FIGS. 15A and 15B. Initially, the device 61 is a sheet formed in a spiral shape as shown in FIG. 15A to present a reduced diameter smaller than the diameter of the formed channel 50. In response to expanding forces (e.g., expansion of a balloon 60 within device 61), device 61 expands to a cylinder as shown in FIG. 15B. Interlocking tabs 61a and recesses 61b on opposing edges of the device 61 define a locking mechanism 62 to retain the device 61 in a cylindrical shape. The cylindrical shape of device 61 after expansion of the balloon 60, as shown in FIG. 15B, is larger in diameter than the spiral shape of device 61 prior to expansion of the balloon 60, as shown in FIG. 15A. The device 61 as expanded is sized to be retained within the formed channel 50 upon expansion.

Throughout this portion of the procedure, the location of this second intraventricular catheter 160 within a chamber of a heart 44 can be ascertained by either indirect visualization employing standard fiber-optic instrumentation inherent to the second intraventricular catheter, or and/or by standard radiographic techniques.

Eleventh, the tip 180 (FIG. 14A) of the second intraventricular catheter 160 is introduced into and advanced within the formed channel 50.

Twelfth, with the tip 180 of the second intraventricular catheter 160 near or abutting the side of the intracoronary catheter balloon 130, a balloon 60 surrounding circumferentially the tip of the second intraventricular catheter 160, is inflated. As shown in FIGS. 14C and 14D, inflation of the balloon 60 causes the device 61 located circumferentially around the balloon 60 located on the end of the second intraventricular catheter 160 to become seated against the walls of the formed channel 50.

As shown in FIG. 16, the device 61, is locked into the cylindrical position when the underlying balloon 60 is inflated by an interlocking mechanism 62 constructed as part of the device 61.

Thirteenth, the balloon 60 on the intraventricular catheter tip is deflated, and the catheter removed from the body, as shown in FIG. 14D.

Fourteenth, a third intraventricular catheter 70 is inserted at the innominate artery access site 142. This third intraventricular catheter 70 is then advanced in a 5 retrograde fashion into a chamber of the left side of a heart, as outlined above.

This third intraventricular catheter 70 is equipped with a hollow tube 71 on its distal tip which can interlock to the device 61 previously placed within the formed channel 50, as shown in FIGS. 17A and 17B.

Fifteenth, the hollow tube 71 is forwarded within the formed channel 50, and 10 interlocked to the device 61. In one embodiment, the hollow tube 71 can partially insert into the device 61 previously seated within the formed channel 50.

The hollow tube 71 can, but may not necessarily, be equipped with a bi-directional flow regulator 74 to provide full blood flow in the direction of arrow C with reduced (but not blocked) blood flow opposite the direction of arrow C. An 15 array of such hollow tubes 71 of various dimensions can be available to the surgeon at the operative procedure.

Sixteenth, the balloon 130 on the end of the intracoronary catheter 120 is deflated.

Seventeenth, angiographic dye can be introduced into a chamber of the heart 20 through a port internal to the third intraventricular catheter 71. The introduction of angiographic dye can allow the blood flow to be visualized under fluoroscopy, digital subtraction angiography, or similar standard techniques. By such radiographic examination, blood flow directly from a chamber of a heart into a coronary artery can be ascertained. In cases where a bi-directional flow regulator 74 25 is utilized, the bi-directional flow from a chamber of a heart and into a coronary artery and the flow rates can be verified.

Eighteenth, the third intraventricular catheter 70 is withdrawn from the body through the innominate incision site 142.

Nineteenth, the intracoronary catheter 120 is withdrawn from the body 30 through the femoral incision site 126.

Twentieth, the sites of the innominate incision 142 and femoral incision 126 are surgically re-approximated through standard closure techniques.

Twenty-first, anesthesia is reversed and the patient revived by standard techniques.

5

Changes and Modifications

Although the foregoing invention has been described in detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that changes and modifications may be practiced within the scope of the appended 10 claims.

What is claimed is:

1. A method for performing a coronary artery bypass procedure for supplementing a flow of blood to a coronary artery, said method comprising: forming a blood flow path from a heart chamber directly to said coronary artery and maintaining said blood flow path open during both systole and diastole.
2. A method according to claim 1 comprising selecting a blood conduit having a first end and a second end and placing said first end in blood flow communication with said chamber and placing said second end in blood flow communication with said coronary artery.
3. A method according to claim 2 wherein said conduit is selected with a cross-sectional area sufficient for blood to flow through said conduit at a volumetric flow rate to effectively reduce signs and symptoms of reduced coronary blood flow.
4. A method according to claim 2 or claim 3 comprising:
 - a. inserting said first end into said chamber through a wall of said chamber and retaining said first end in said wall and in blood flow communication with said blood within said chamber; and
 - b. inserting said second end into said coronary artery and retaining said second end in said coronary artery and in blood flow communication with a lumen of said coronary artery.
5. A method according to any one of claims 1 to 4 wherein said coronary artery is at least partially obstructed at a predetermined site, said method further comprising forming said path directly to said coronary artery downstream of said site.
6. A method according to any one of claims 1 to 5 further comprising reducing but not blocking blood flow through said path during diastole.

7. A method according to any one of claims 1 to 6 comprising directing blood flow through said path to reduce direct impingement of said blood flow upon a wall of the coronary artery.

8. A method according to any one of claims 1 to 7 comprising forming said path through said wall and through a lower wall of said artery.

9. An apparatus for use in a coronary artery bypass procedure for supplementing a flow of blood to a coronary artery, said apparatus comprising:

- a. a blood flow conduit having a first end adapted to be inserted into and retained within a wall of a heart chamber containing oxygenated blood with said first end in blood flow communication with blood contained within said chamber;
- b. said conduit having a second end adapted to be inserted into and retained within said coronary artery with said second end in blood flow communication with a lumen of said coronary artery; and
- c. said conduit adapted to define an open blood flow path during both diastole and systole.

10. An apparatus according to claim 9 wherein said conduit has a cross-sectional area sufficient to pass blood at a volumetric flow rate to supply blood to cardiac musculature served by said coronary artery in an amount to reduce signs and symptoms of reduced coronary blood flow.

11. An apparatus according to claim 9 or claim 10 wherein said conduit has a geometry selected to bias forward flow of blood from said first end toward said second end while not blocking blood flow from a direction from said second end toward said first end.

12. An apparatus according to any one of claims 9 to 11 wherein said second end is sized to be inserted into and retained within said coronary artery on a downstream side of a predetermined obstruction site.
13. An apparatus according to any one of claims 9 to 12 comprising a deflection surface for blocking blood flow through said conduit from impinging directly upon said coronary artery.
14. An apparatus according to any one of claims 9 to 13 wherein said conduit is sized to extend through said heart chamber wall and a lower wall of said coronary artery.
15. An apparatus according to any one of claims 1 to 14 wherein said conduit is biased for a net volumetric blood flow from said first end toward said second end.
16. An apparatus according to any one of claims 9 to 15 in which there is provided in the conduit means for reducing but not blocking blood flow through said blood flow path during diastole.
17. An apparatus for use in the treatment of coronary artery disease, said apparatus comprising:
 - a. a blood flow conduit having a first end adapted to be inserted into and retained within a wall of a heart chamber containing oxygenated blood with said first end in blood flow communication with blood contained within said chamber.
 - b. said conduit having a second end adapted to be inserted into and retained within said coronary artery with said second end in blood flow communication with a lumen of said coronary artery; and
 - c. said conduit adapted to define an open blood flow path during both diastole and systole.

18. An apparatus according to claim 17 comprising a deflection surface that is so arranged relative to said first end of said conduit that, in use, blood flow in a first flow direction from said first end of said conduit is diverted to a second flow direction.
19. An apparatus according to claim 18, wherein said deflection surface is a portion of a wall of said conduit.
20. An apparatus according to any one of claims 17 to 19, in which the conduit is so configured that, in use, a first portion of said conduit comprising said first end extends from said chamber through a wall of said coronary artery and a second portion along a portion of said lumen of said coronary artery.
21. An apparatus according to claims 20, wherein said second portion extends in a direction that is substantially perpendicular to or at an oblique angle relative to the direction in which said first portion extends.
22. An apparatus according to claims 21, wherein said conduit is defined by a continuous wall extending from said first end to said second end, said apparatus being suitable in use for substantially complete replacement of coronary arterial flow in said coronary artery.
23. An apparatus according to any one of claims 17 to 21, which is so constructed that in use blood flow from a portion of said lumen located upstream of said conduit is confluent with said blood flow path, said apparatus being suitable in use for supplementation of coronary arterial flow.
24. An apparatus according to any one of claims 17 to 23, in which said first end of said conduit comprises retention means which are so arranged that, in use of the apparatus, they are able to retain said first end in position in said chamber wall.

25. A kit of parts for assembly to form an apparatus according to any one of claims 9 to 24, said kit comprising a first part comprising a first end adapted to be inserted into and retained within said chamber wall and a second part comprising a deflection surface for blocking blood flow through said first part from impinging directly upon said coronary artery.

26. The use in the preparation of an apparatus for the treatment of coronary heart disease of a device comprising:

- a. a blood flow conduit having a first end adapted to be inserted into and retained within a wall of a heart chamber containing oxygenated blood with said first end in blood flow communication with blood contained within said chamber;
- b. said conduit having a second end adapted to be inserted into and retained within said coronary artery with said second end in blood flow communication with a lumen of said coronary artery; and
- c. said conduit adapted to define an open blood flow path during both diastole and systole.

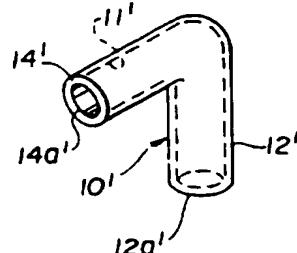
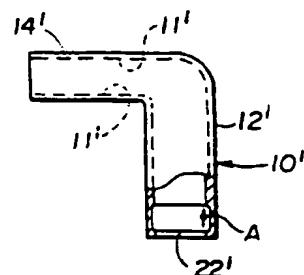
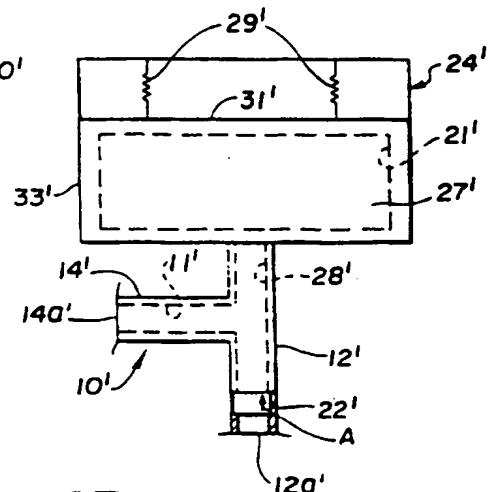
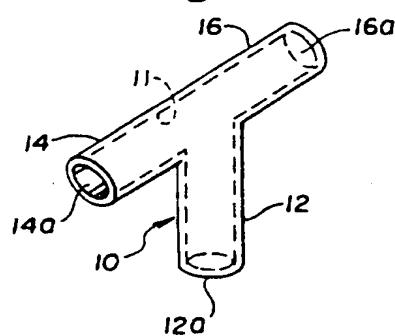
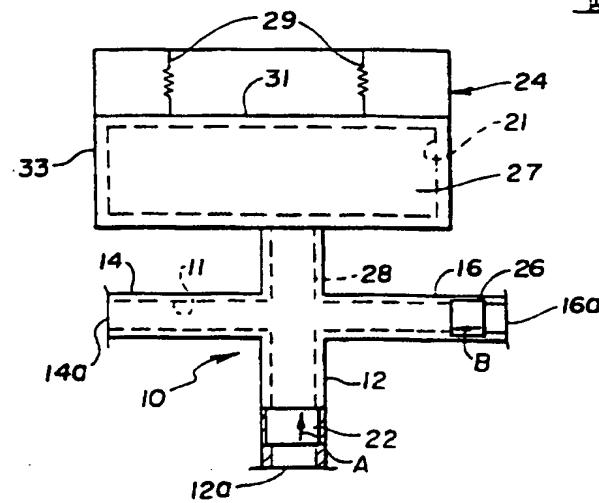
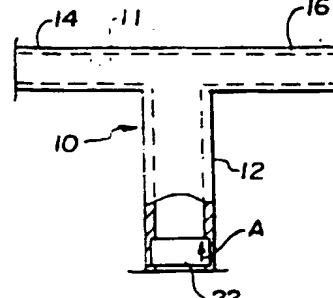
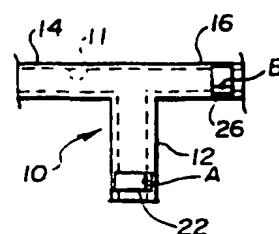
Fig.1A**Fig.1B****Fig.1C****Fig.2A****Fig.2B****Fig.2C**

Fig. 3C

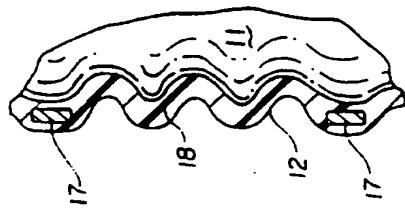


Fig. 3B

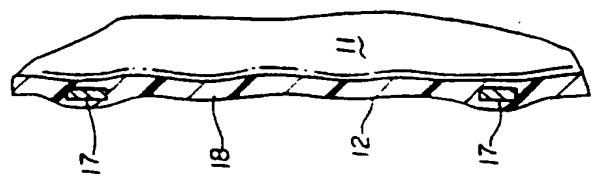


Fig. 3A

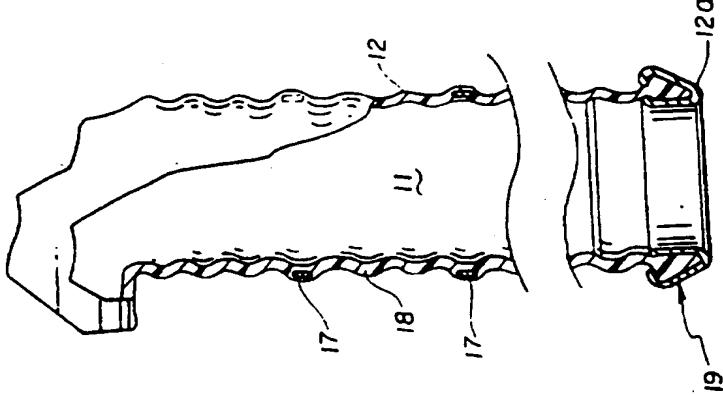


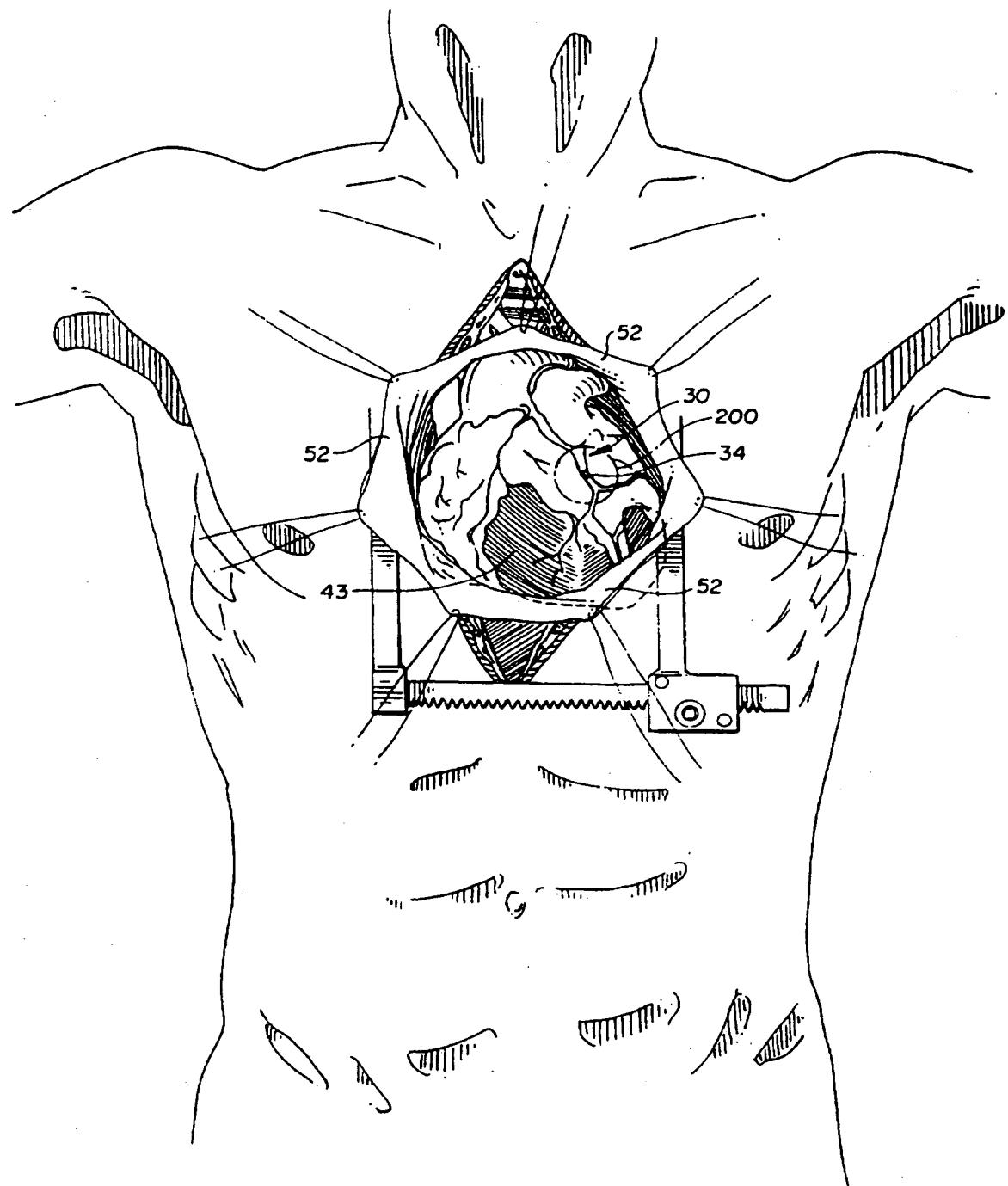
Fig. 4

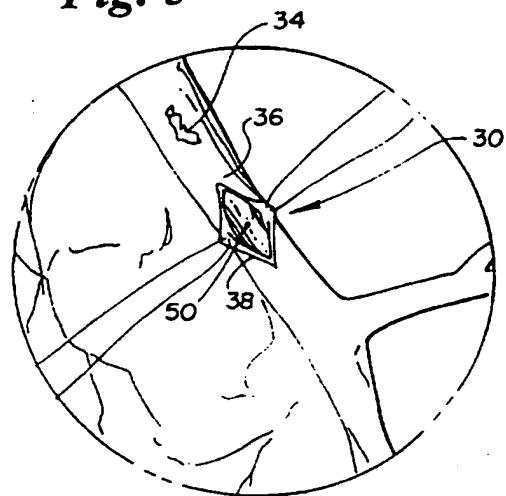
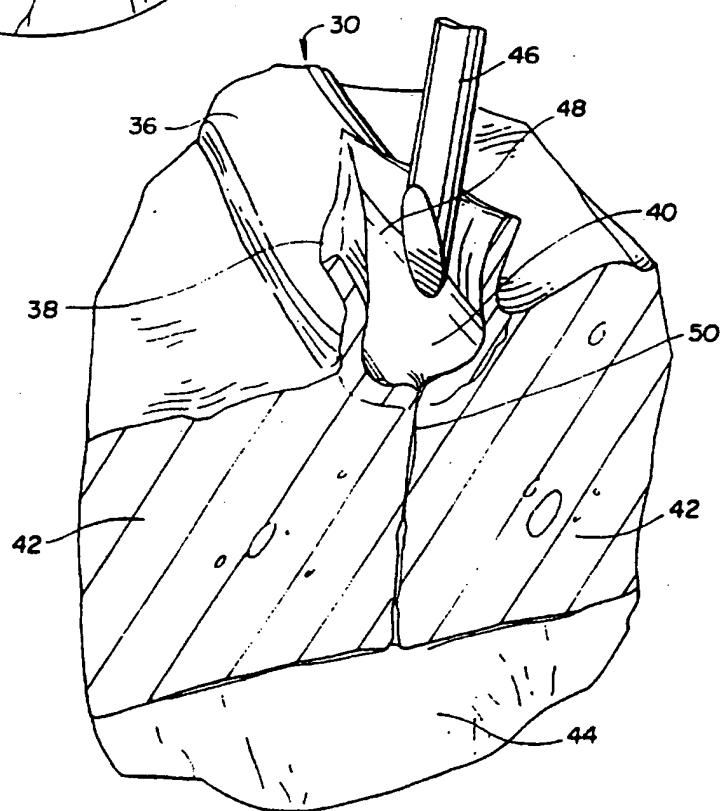
Fig. 5*Fig. 6*

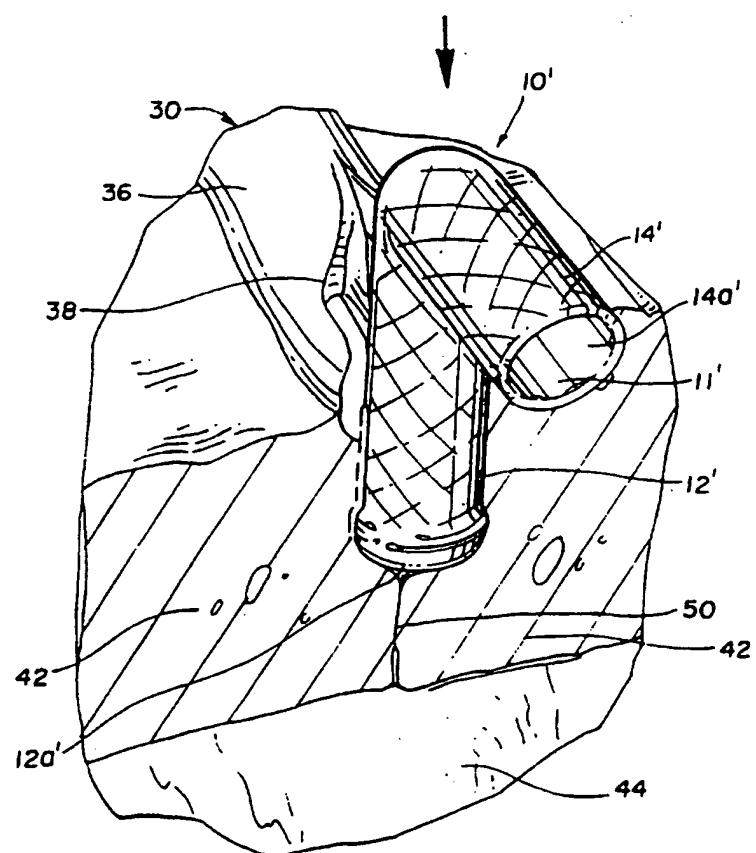
Fig. 7

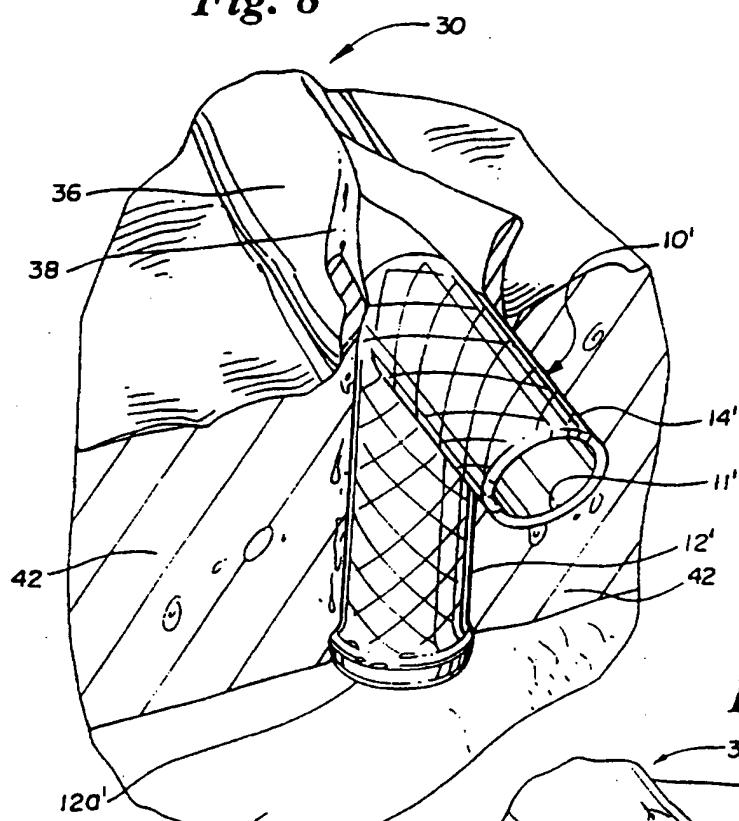
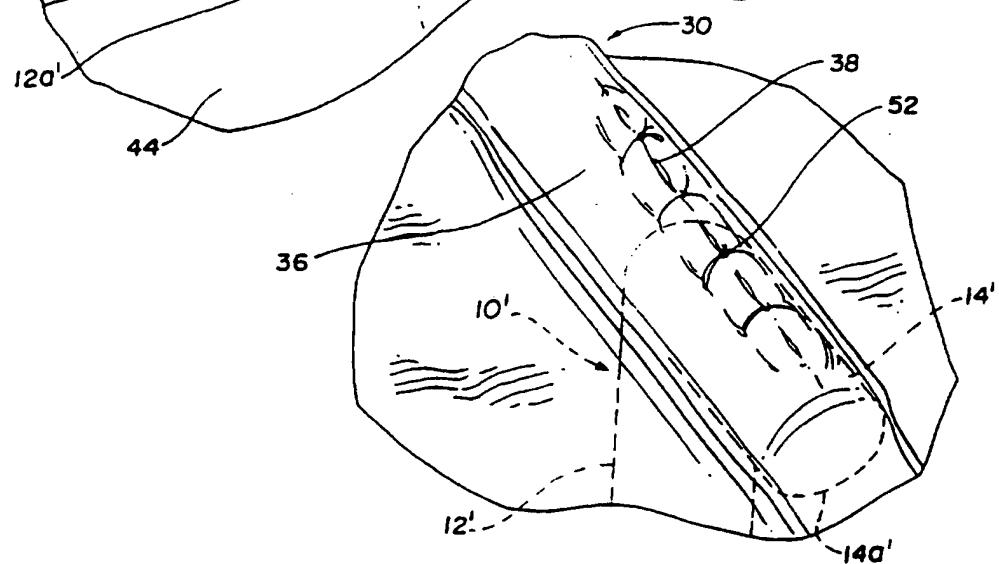
Fig. 8*Fig. 9*

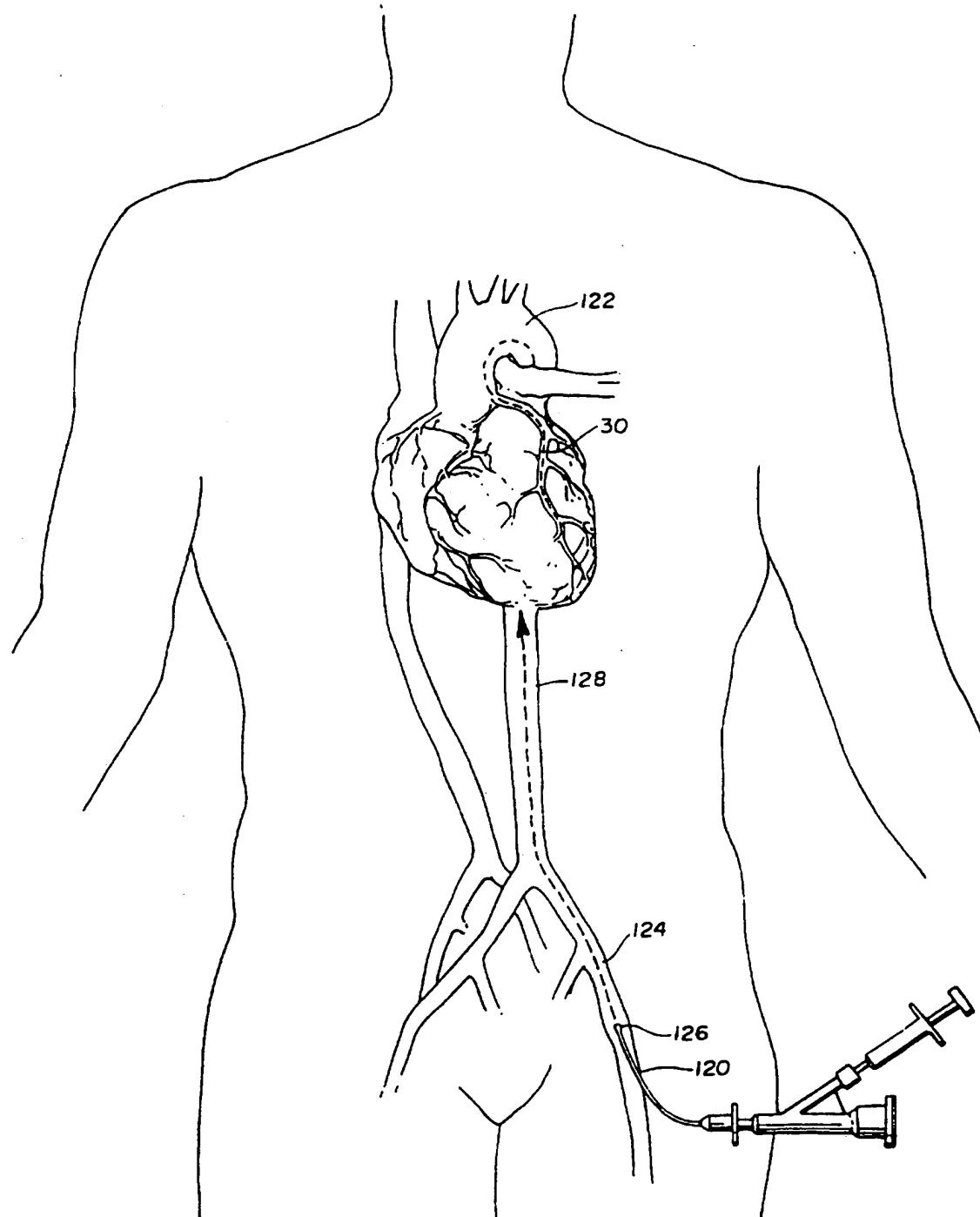
Fig. 10

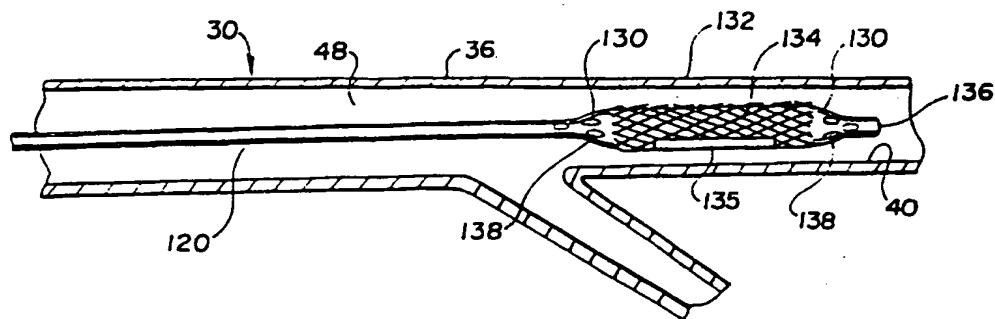
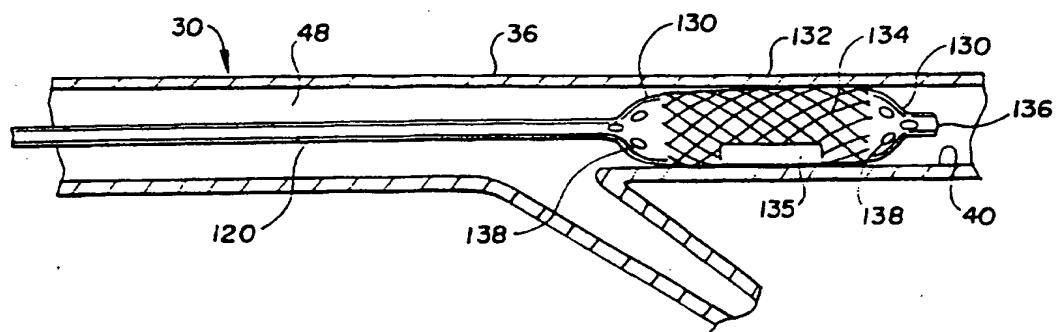
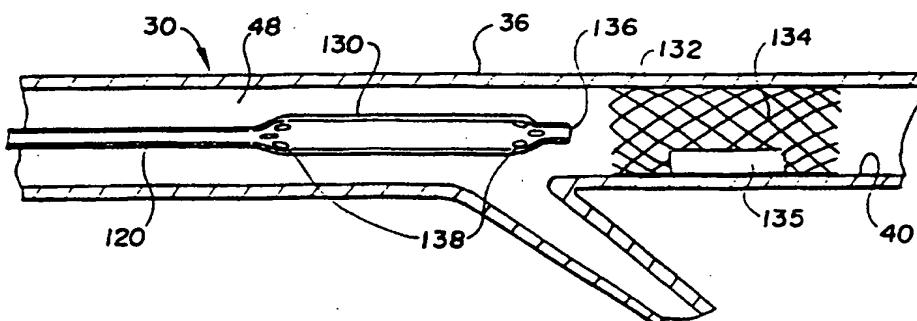
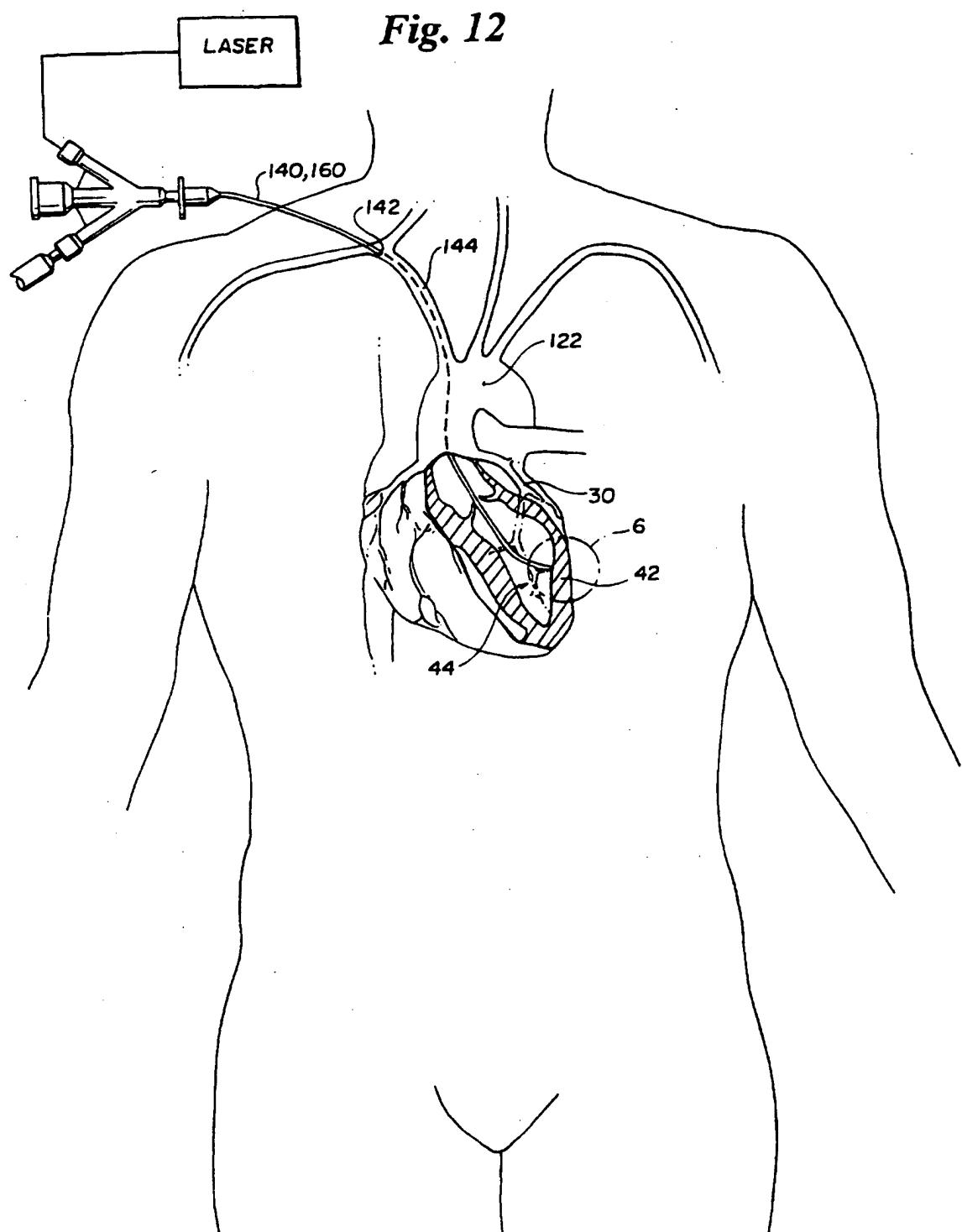
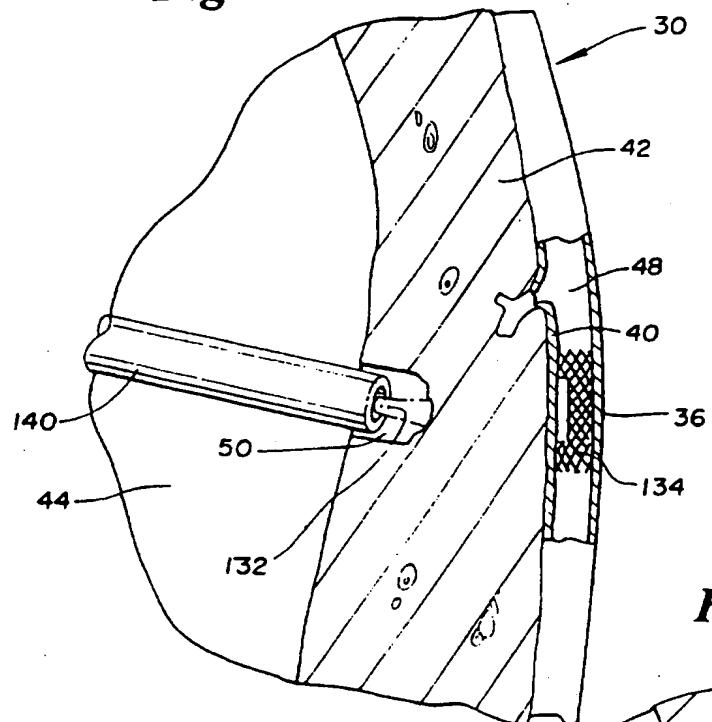
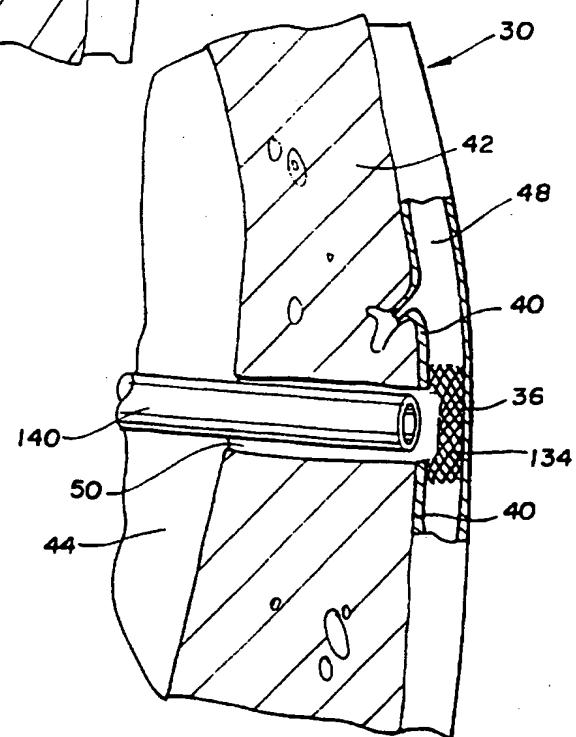
Fig.11A**Fig.11B****Fig.11C**

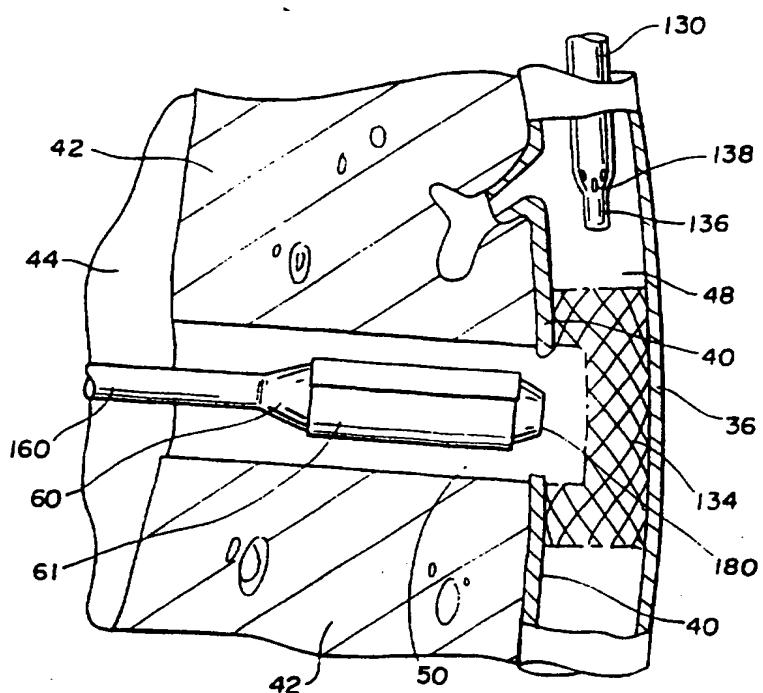
Fig. 12

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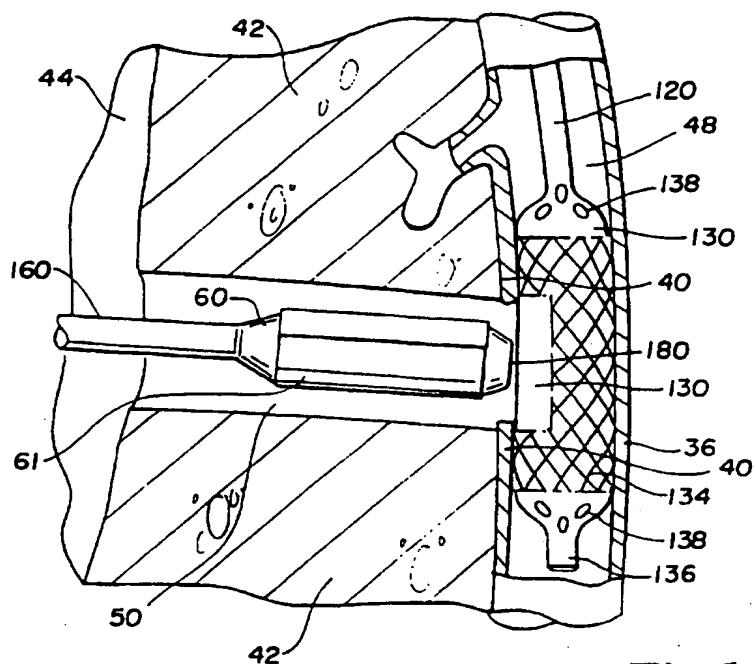
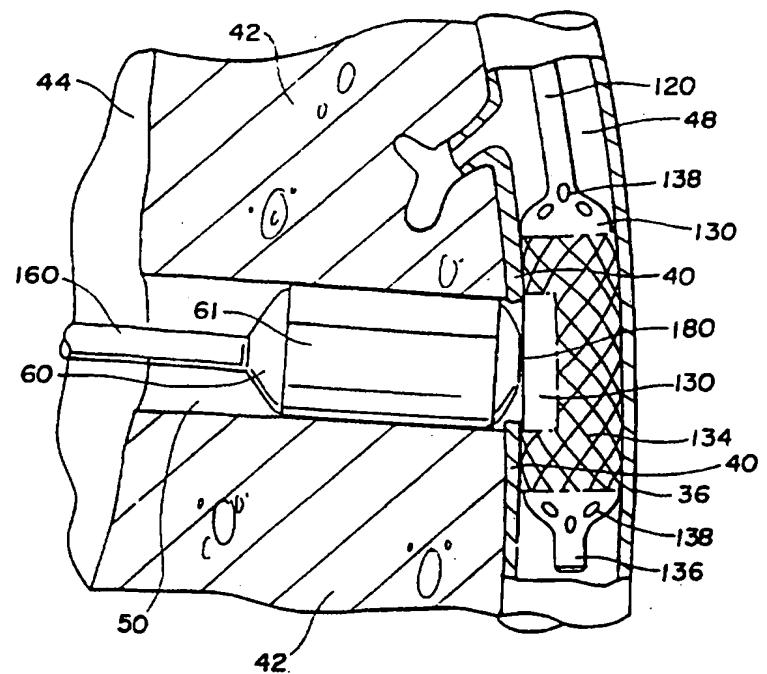
Fig.13A*Fig.13B*

SUBSTITUTE SHEET (RULE 26)

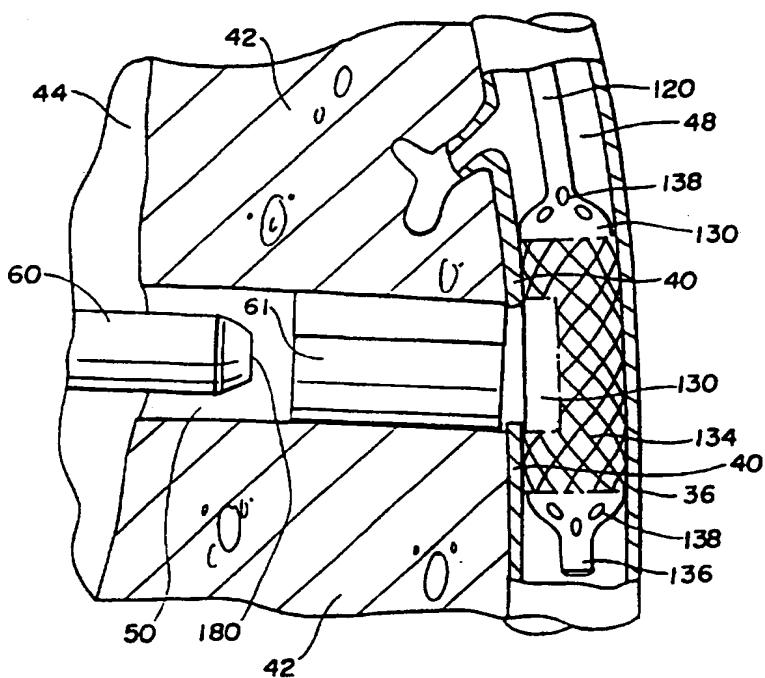
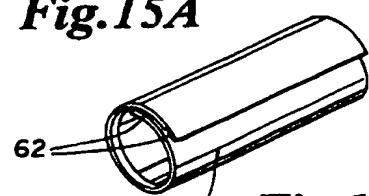
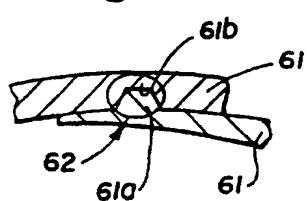
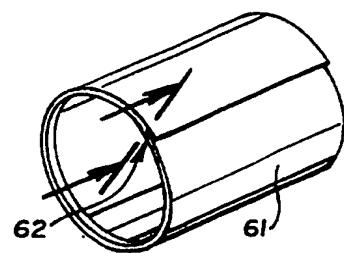
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Fig.14A

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Fig.14B**Fig.14C****SUBSTITUTE SHEET (RULE 26)**

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Fig.14D*Fig.15A**Fig. 16**Fig.15B*

SUBSTITUTE SHEET (RULE 26)

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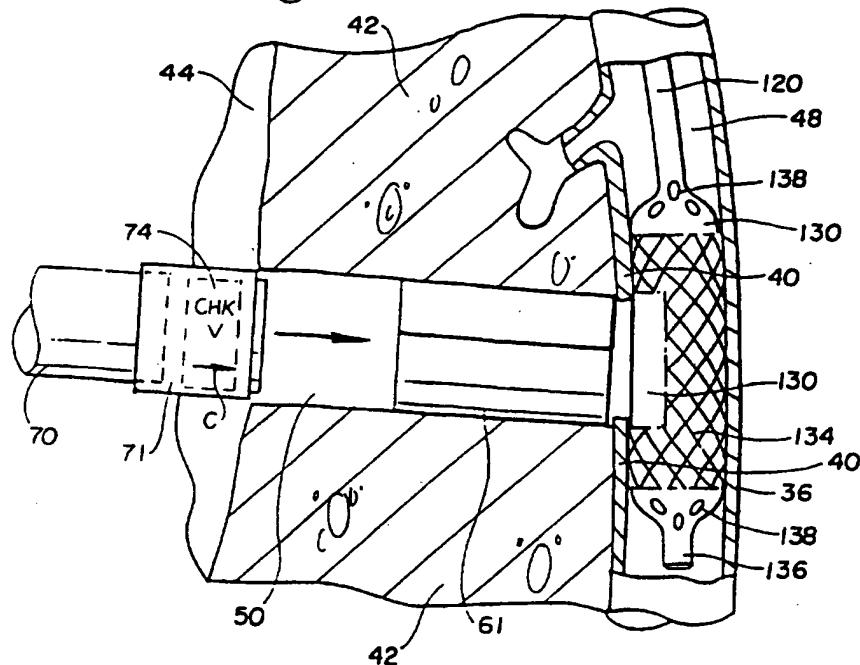
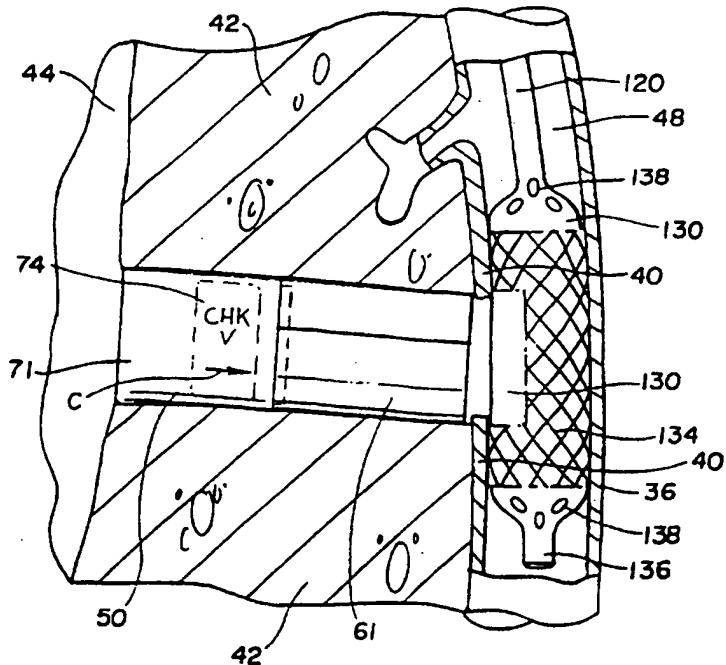
Fig.17A**Fig.17B**

FIG. 18A

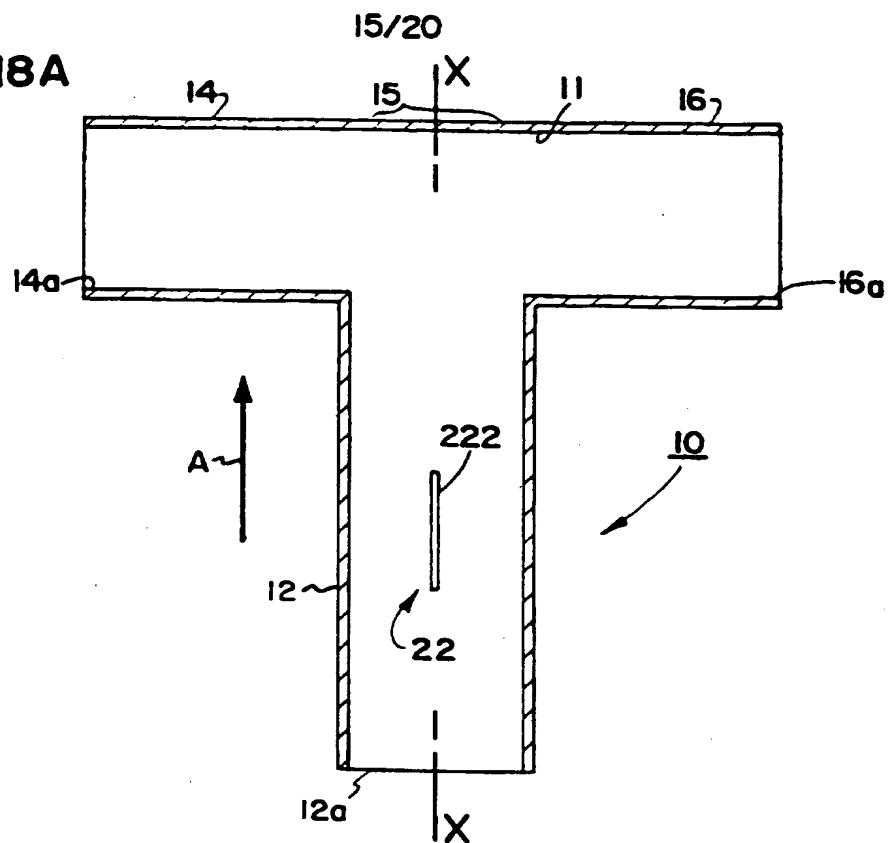
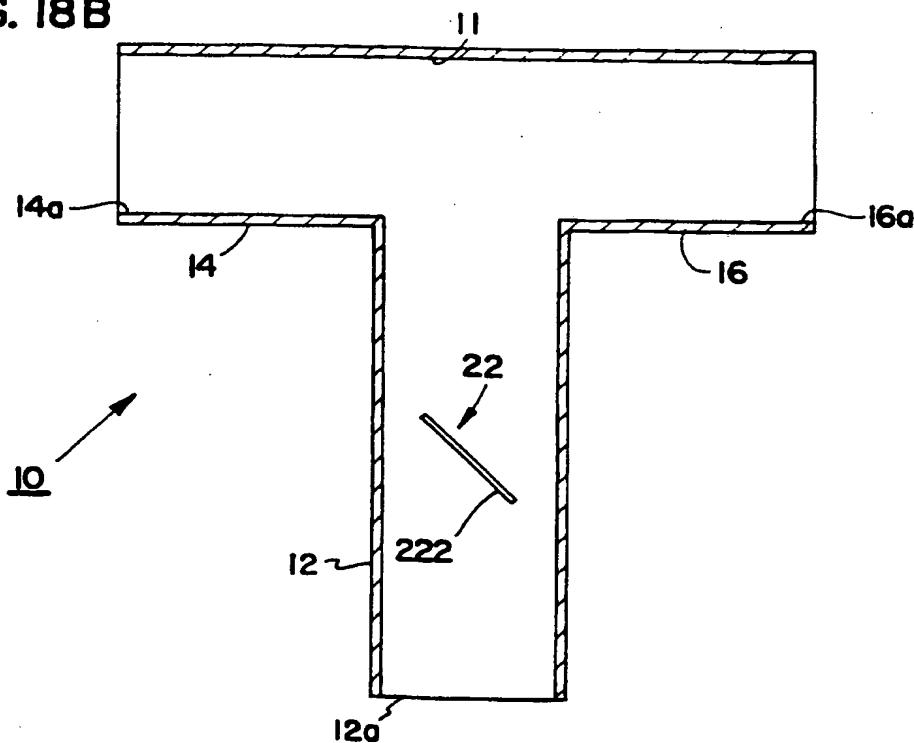


FIG. 18B



SUBSTITUTE SHEET (RULE 26)

FIG. 18C

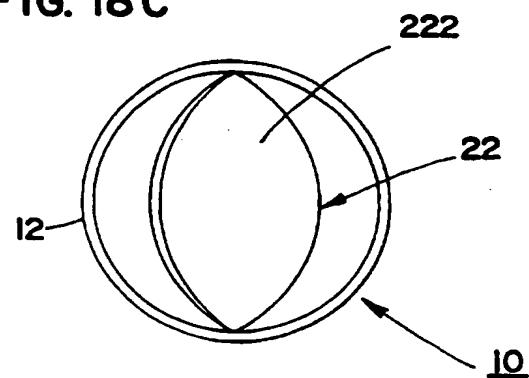
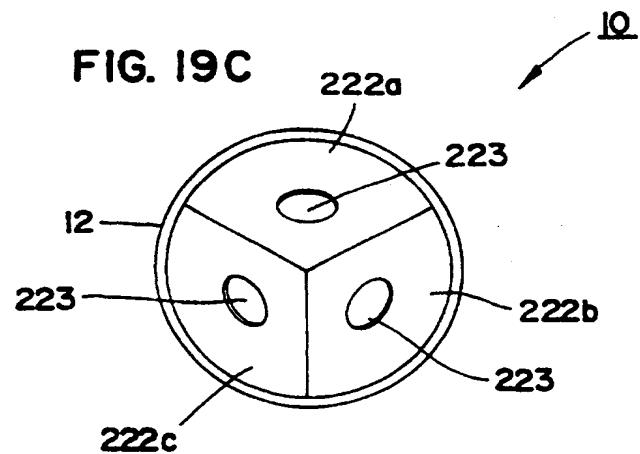
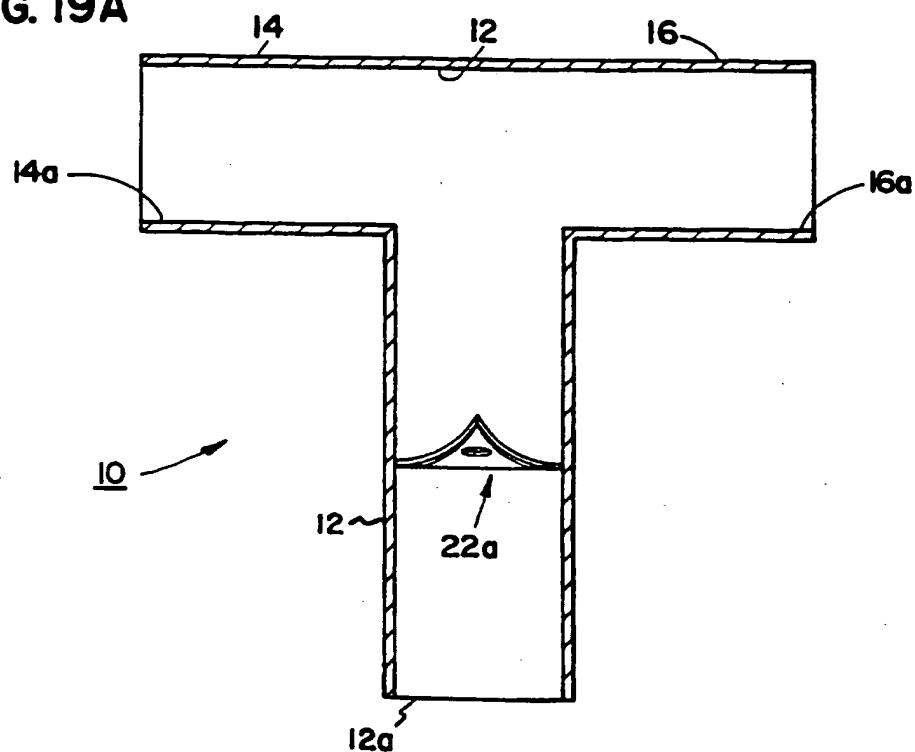
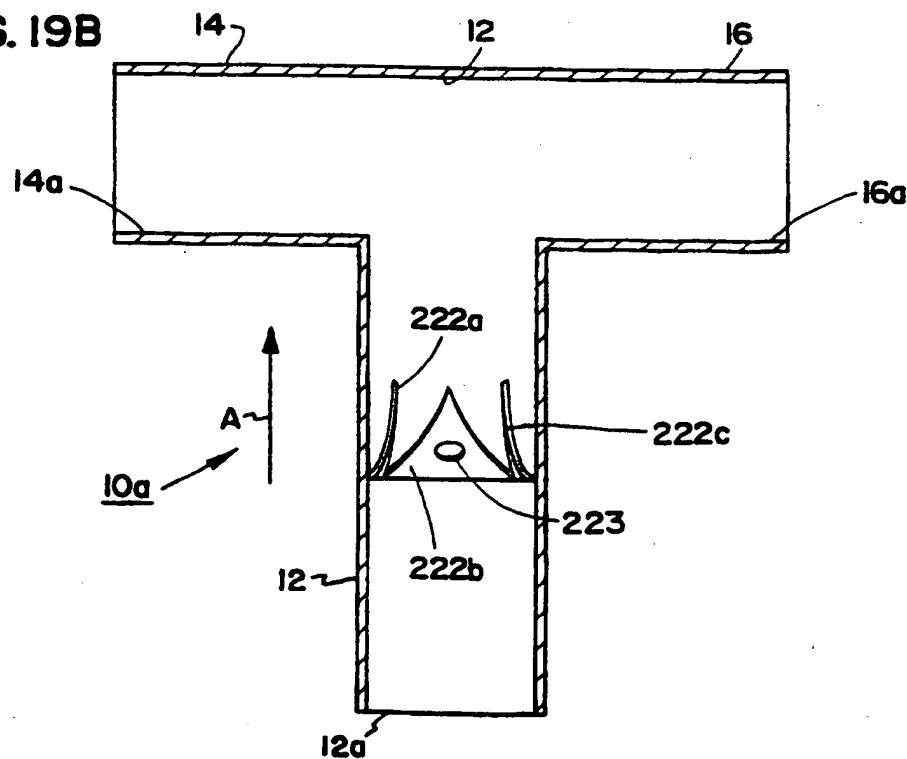


FIG. 19C



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FIG. 19A**FIG. 19B****SUBSTITUTE SHEET (RULE 26)**

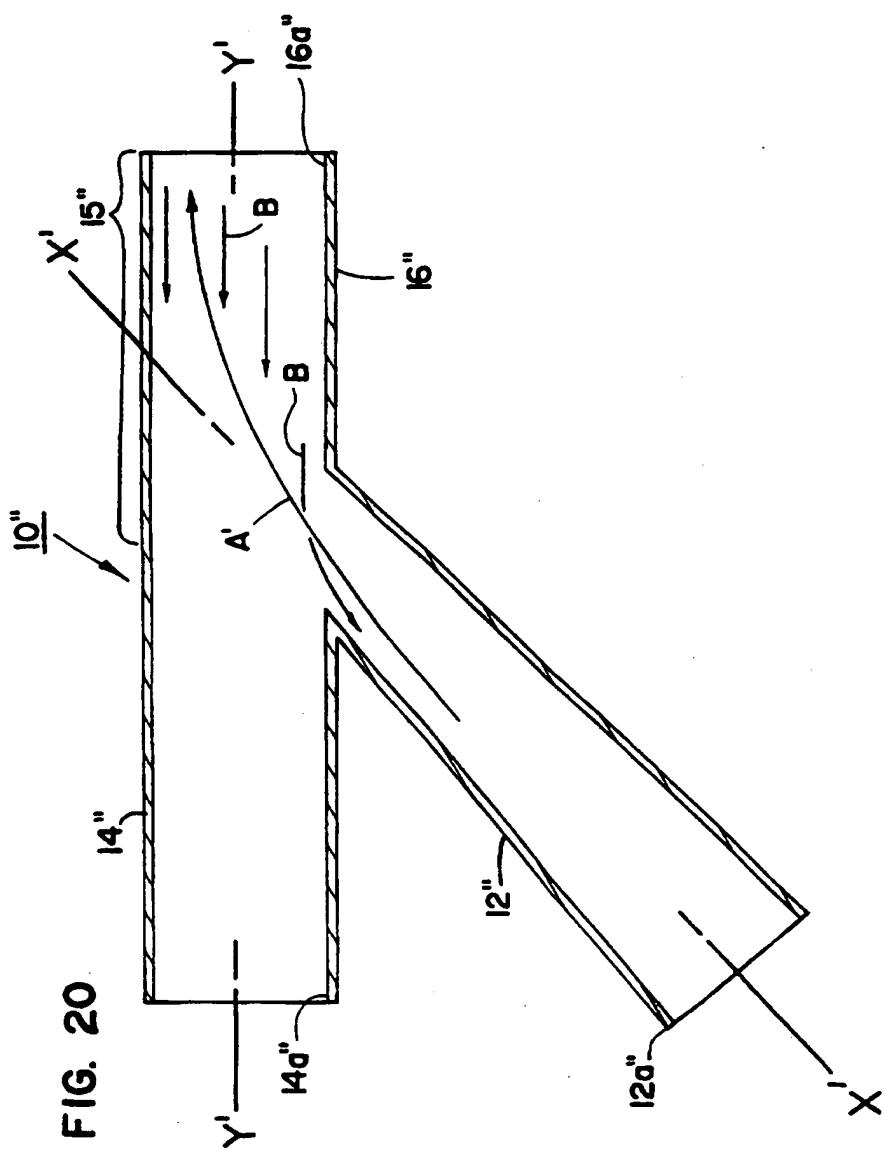


FIG. 20

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FIG. 21

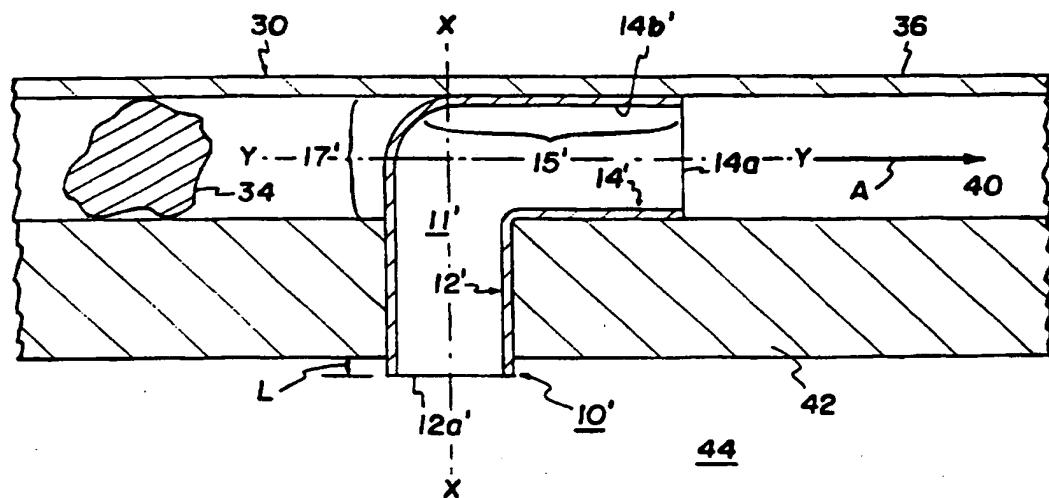


FIG. 22

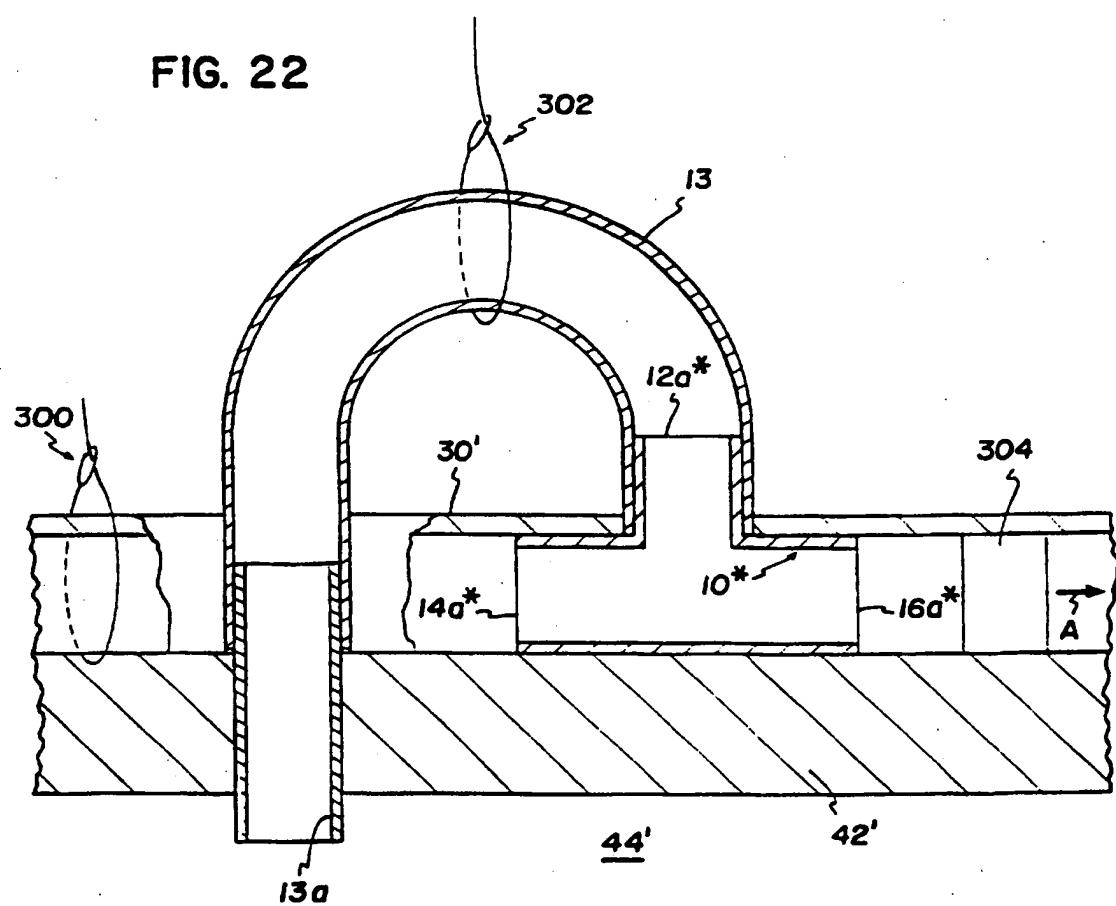
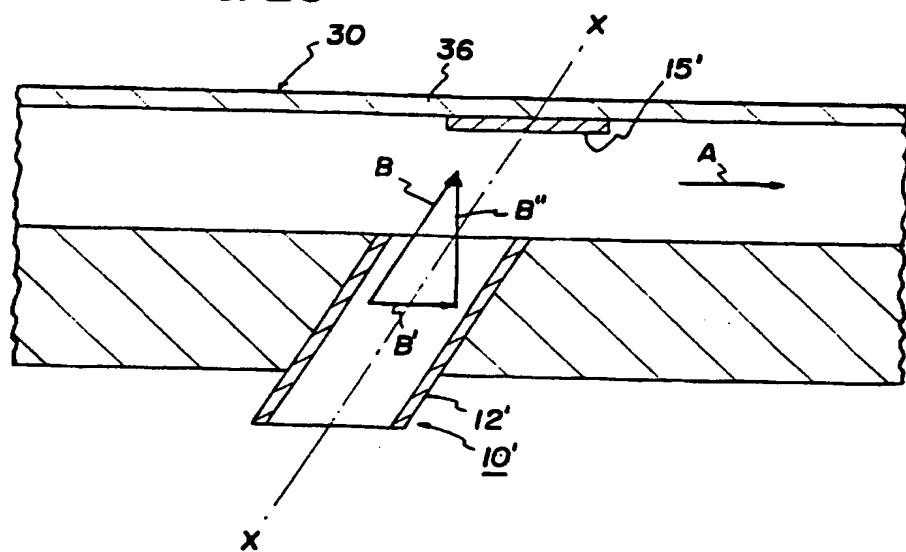


FIG. 23



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/13980

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 429 144 A (WILK) 4 July 1995 cited in the application see the whole document ----	9,17,25
A	US 4 712 551 A (RAYHANABAD) 15 December 1987 ----	
A	US 4 769 031 A (MCGOUGH ET AL) 6 September 1988 ----	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

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Date of the actual completion of the international search

3 December 1997

Date of mailing of the international search report

11.12.97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel: (+31-70) 340-2040, Tx. 31 651 epo nl
Fax: (+31-70) 340-3016

Authorized officer

Smith, C

INTERNATIONAL SEARCH REPORT

In national application No
PCT/US 97/13980

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: **1-8, 26**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6 4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/13980

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5429144 A	04-07-95	US 5409019 A US 5287861 A	25-04-95 22-02-94
US 4712551 A	15-12-87	NONE	
US 4769031 A	06-09-88	NONE	